[Code of Federal Regulations]

[联 邦 法 规]

[Title 21, Volume 8]

[标题 21，第 8 卷]

[CITE: 21 CFR 803]

[引用：21 CFR 803]

TITLE 21--FOOD AND DRUGS

标题21--食品和药品

CHAPTER I--FOOD AND DRUG ADMINISTR

第I章--食品和药品管理局

ATION DEPARTMENT OF HEALTH AND HUMAN SERVICES

卫生与公众服务部

SUBCHAPTER H - MEDICAL DEVICES

H分章-医疗器械

Part 803 Medical Device Reporting

第803部分 医疗器械报告

Content（目录）

Subpart A - General Provisions	**A** 分部 **-** 一般规定
§ 803.1 What does this part cover?	**§** 803.1 这部分包括什么？
(a) This part establishes the requirements for medical device reporting for device user facilities, manufacturers, importers, and distributors. If you are a device user facility, you must report deaths and serious injuries that a device has or may have caused or contributed to, establish and maintain adverse event files, and submit summary annual reports. If you are a manufacturer or importer, you must report deaths and serious injuries that your device has or may have caused or contributed to, you must report certain device malfunctions, and you must establish and maintain adverse event files. If you are a manufacturer, you must also submit specified followup. These reports help us to protect the public health by helping to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use. If you are a medical device distributor, you must maintain records (files) of incidents, but you are not required to report these incidents.	(a) 本部分规定了器械用户设施、制造商、进口商和分销商的医疗器械报告要求。如果您是设备用户机构，您必须报告设备已经或可能已经导致或促成的死亡和严重伤害，建立和维护不良事件文件，并提交年度总结报告。如果您是制造商或进口商，您必须报告您的设备已经或可能已经造成或促成的死亡和严重伤害，您必须报告某些设备故障，并且您必须建立和维护不良事件文件。如果您是制造商，您还必须提交指定的跟进。这些报告帮助我们确保设备没有掺假或贴错标签，并且对于其预期用途是安全有效的，从而帮助我们保护公众健康。
(b) This part supplements and does not supersede other provisions of this chapter, including the provisions of part 820 of this chapter.	(b) 本部分补充而不取代本章的其他规定，包括本章第 820 部分的规定。
(c) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.	(c) 除非另有说明，否则本部分中对联邦法规法典的监管部分的引用是指第 21 篇第 I 章。
§ 803.3 How does FDA define the terms used in this part?	**§**803.3 FDA 如何定义本部分中使用的术语？
Some of the terms we use in this part are specific to medical device reporting and reflect the language used in the statute (law). Other terms are more general and reflect our interpretation of the law. This section defines the following terms as used in this part:	我们在本部分中使用的一些术语专门针对医疗器械报告，并反映了法规（法律）中使用的语言。其他术语更为笼统，反映了我们对法律的解释。本节定义了本部分中使用的以下术语：
(a) Ambulatory surgical facility (ASF) means a distinct entity that operates for the primary purpose of furnishing same day outpatient surgical services to patients. An ASF may be either an independent entity (i.e., not a part of a provider of services or any other facility) or operated by another medical entity (e.g., under the common ownership, licensure, or control of an entity). An ASF is subject to this regulation regardless of whether it is licensed by a Federal,	(a)门诊手术设施 (ASF) 是指以向患者提供当日门诊手术服务为主要目的的独立实体。ASF 可以是一个独立的实体（即，不是服务提供者或任何其他设施的一部分）或由另一个医疗实体运营（例如，在一个实体的共同所有权、许可或控制下）。无论 ASF 是否获得联邦、州、市

State, municipal, or local government or regardless of whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the ASF must report that event regardless of the nature or location of the medical service provided by the ASF.	或地方政府的许可，也无论其是否获得认可的认证机构的认证，都必须遵守该法规。如果不良事件符合报告标准，无论 ASF 提供的医疗服务的性质或地点如何，ASF 都必须报告该事件。
(b) Become aware means that an employee of the entity required to report has acquired information that reasonably suggests a reportable adverse event has occurred.	(b)意识到 是指被要求报告的实体的员工已获得合理暗示已发生可报告不良事件的信息。
(1) If you are a device user facility, you are considered to have "become aware" when medical personnel, as defined in this section, who are employed by or otherwise formally affiliated with your facility, obtain information about a reportable event.	(1) 如果您是设备用户机构，当您的机构雇用或以其他方式正式隶属于您的机构的医务人员（如本 节所定义）获得有关可报告事件的信息时，您将被视为"意识到"。
(2) If you are a manufacturer, you are considered to have become aware of an event when any of your employees becomes aware of a reportable event that is required to be reported within 30 calendar days or that is required to be reported within 5 work days because we had requested reports in accordance with § 803.53(b). You are also considered to have become aware of an event when any of your employees with management or supervisory responsibilities over persons with regulatory, scientific, or technical responsibilities, or whose duties relate to the collection and reporting of adverse events, becomes aware, from any information, including any trend analysis, that a reportable MDR event or events necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health.	(2) 如果您是制造商，当您的任何员工发现需要在 30 个日历日内报告或需要在 5 个工作时间内报告的可报告事件时，您将被视为已了解事件天，因为我们已根据 § 803.53(b) 要求报告。当您的任何员工对负有监管、科学或技术责任的人员或其职责与收集和报告不良事件有关的人员负有管理或监督责任时，您也被视为已从任何信息，包括任何趋势分析，表明一个或多个可报告的 MDR 事件需要采取补救措施，以防止对公众健康造成重大损害的不合理风险。
(3) If you are an importer, you are considered to have become aware of an event when any of your employees becomes aware of a reportable event that is required to be reported by you within 30 days.	(3) 如果您是进口商，当您的任何员工发现您需要在 30 天内报告的可报告事件时，您将被视为已了解事件。
(c) Caused or contributed means that a death or serious injury was or may have been attributed to a medical device, or that a medical device was or may have been a factor in a death or serious injury, including events occurring as a result of:	(c)造成或促成 是指死亡或严重伤害已经或可能已经归因于医疗器械，或者医疗器械曾经或可能已经成为死亡或严重伤害的一个因素，包括由于以下原因而发生的事件：
(1) Failure, (2) Malfunction,	(1) 失败， (2) 故障，

(3) Improper or inadequate design, (4) Manufacture, (5) Labeling, or (6) User error.	(3) 设计不当或不充分， (4) 制造， (5) 标签，或 (6) 用户错误。
(d) Device user facility means a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility as defined in this section, which is not a physician's office, as defined in this section. School nurse offices and employee health units are not device user facilities.	(d)设备用户设施 是指本节定义的医院、门诊手术设施、疗养院、门诊诊断设施或门诊治疗设施，而不是本节定义的医生办公室。学校护士办公室和员工健康单位不是设备用户设施。
(e) Distributor means any person (other than the manufacturer or importer) who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the container, wrapper, or labeling of the device or device package. If you repackage or otherwise change the container, wrapper, or labeling, you are considered a manufacturer as defined in this section.	(e)分销商 是指任何人（制造商或进口商除外）将设备从原始制造地推向最终交付或销售给最终用 户的人，但不重新包装或以其他方式改变设备或设备包装的容器、包装或标签。如果您重新包装或以其他方式更改容器、包装或标签，您将被视为本节定义的制造商。
(f) Expected life of a device means the time that a device is expected to remain functional after it is placed into use. Certain implanted devices have specified “end of life” (EOL) dates. Other devices are not labeled as to their respective EOL, but are expected to remain operational through activities such as maintenance, repairs, or upgrades, for an estimated period of time.	(f)设备的预期寿命是 指设备在投入使用后预期保持功能的时间。某些植入设备已指定“寿命终止” (EOL) 日期。其他设备未标记其各自的 EOL，但预计将在估计的一段时间内通过维护、维修或升级等活动保持运行。
(g) FDA, we, us, or Agency means the Food and Drug Administration.	(g) FDA、我们、我们或机构 是指食品和药物管理局。
(h) Five-day report means a medical device report that must be submitted by a manufacturer to us under §803.53 within 5 work days.	(h)五天报告 是指制造商必须在 5 个工作日内根据 § 803.53 向我们提交的医疗器械报告。
(i) Hospital means a distinct entity that operates for the primary purpose of providing diagnostic, therapeutic (such as medical, occupational, speech, physical), surgical, and other patient services for specific and general medical conditions. Hospitals include general, chronic disease, rehabilitative, psychiatric, and other special-purpose facilities. A hospital may be either independent (e.g., not a part of a provider of services or any other facility) or may be operated by another medical entity (e.g., under the common ownership, licensure, or control of another entity). A hospital is	(i)医院 指以提供诊断、治疗（例如医疗、职业、语言、身体）、手术和其他针对特定和一般医疗状况的患者服务为主要目的的独立实体。医院包括普通、慢性病、康复、精神病和其他特殊用途的设施。医院可以是独立的（例如，不是服务提供者或任何其他设施的一部分），也可以由另一个医疗实体运营（例如，在另一个实体的共同所有权、许可或控制下）。

covered by this regulation regardless of whether it is licensed by a Federal, State, municipal or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the hospital must report that event regardless of the nature or location of the medical service provided by the hospital.	无论医院是否获得联邦、州、市或地方政府的许可，或者是否获得公认的认证机构的认证，医院都受本法规的约束。如果不良事件符合报告标准，
(j) Importer means any person who imports a device into the United States and who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the container, wrapper, or labeling of the device or device package. If you repackage or otherwise change the container, wrapper, or labeling, you are considered a manufacturer as defined in this section.	(j)进口商 是指将器械进口到美国的任何人，并将器械从原始生产地推向最终交付或销售给最终用户的人，但不重新包装或以其他方式更改设备或设备包装的容器、包装或标签。如果您重新包装或以其他方式更改容器、包装或标签，您将被视为本节定义的制造商。
(k) Malfunction means the failure of a device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the device. The intended performance of a device refers to the intended use for which the device is labeled or marketed, as defined in § 801.4 of this chapter.	(k)故障 是指设备未能满足其性能规格或按预期执行。性能规格包括设备标签中的所有声明。设备的预期性能是指设备标记或销售的预期用途，如本章第 801.4 节所定义。
(l) Manufacturer means any person who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedure. The term includes any person who either:	(l)制造商 是指通过化学、物理、生物或其他程序制造、制备、繁殖、复合、组装或加工设备的任何人。该术语包括任何符合以下条件的人：
(1) Repackages or otherwise changes the container, wrapper, or labeling of a device in furtherance of the distribution of the device from the original place of manufacture;	(1) 重新包装或以其他方式更改器械的容器、包装或标签，以促进器械从原始制造地的分销；
(2) Initiates specifications for devices that are manufactured by a second party for subsequent distribution by the person initiating the specifications;	(2) 为由第二方制造的设备发起规范，以供发起规范的人随后分发；
(3) Manufactures components or accessories that are devices that are ready to be used and are intended to be commercially distributed and intended to be used as is, or are processed by a licensed practitioner or other qualified person to meet the needs of a particular patient; or	(3) 制造的组件或附件是准备好使用并打算进行商业分销并打算按原样使用的设备，或由有执照的从业者或其他合格人员加工以满足特定患者的需求; 或者
(4) Is the U.S. agent of a foreign manufacturer.	(4) 是外国制造商的美国代理。
(m) Manufacturer or importer report number. This number uniquely	(m)制造商或进口商报告编号。 该编号唯

identifies each individual adverse event report submitted by a manufacturer or importer. This number consists of the following three parts:	一标识制造商或进口商提交的每个单独的不良事件报告。这个数字由以下三部分组成：
(1) The FDA registration number for the manufacturing site of the reported device, or the registration number for the importer. If the manufacturing site or the importer does not have an establishment registration number, we will assign a temporary MDR reporting number until the site is registered in accordance with part 807 of this chapter. We will inform the manufacturer or importer of the temporary MDR reporting number;	(1) 申报器械生产地的FDA注册号，或进口商的注册号。如果生产场所或进口商没有企业注册编号，我们将分配一个临时 MDR 报告编号，直到该场所根据本章第 807 部分进行注册。我们将通知制造商或进口商临时 MDR 报告编号；
(2) The four-digit calendar year in which the report is submitted; and	(2) 提交报告的四位数日历年；和
(3) The five-digit sequence number of the reports submitted during the year, starting with 00001. (For example, the complete number will appear as follows: 1234567-2011-00001.)	(3) 当年提交的报告的五位序列号，从00001开始。（例如，完整的编号会出现如下：1234567- 2011-00001。）
(n) MDR means medical device report.	(n) MDR 是指医疗器械报告。
(o) MDR reportable event (or reportable event) means:	(o) MDR 可报告事件（或可报告事件）是指：
(1) An event that user facilities become aware of that reasonably suggests that a device has or may have caused or contributed to a death or serious injury or	(1) 用户设施意识到的事件合理地表明设备已经或可能已经导致或促成了死亡或重伤，或
(2) An event that manufacturers or importers become aware of that reasonably suggests that one of their marketed devices:	(2) 制造商或进口商意识到的事件合理地表明其销售的设备之一：
(i) May have caused or contributed to a death or serious injury, or	(i) 可能造成或促成了死亡或重伤，或
(ii) Has malfunctioned and that the device or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.	(ii) 发生故障，并且如果故障再次发生，制造商或进口商销售的设备或类似设备可能会导致或导致死亡或严重伤害。
(p) Medical personnel means an individual who:	(p)医务人员 是指符合以下条件的个人：
(1) Is licensed, registered, or certified by a State, territory, or other governing body, to administer health care;	(1) 获得州、领地或其他管理机构的许可、注册或认证，以管理医疗保健；
(2) Has received a diploma or a degree in a professional or scientific discipline;	(2) 已获得专业或科学学科的文凭或学位；
(3) Is an employee responsible for receiving medical complaints or adverse event reports; or	(3) 是负责接收医疗投诉或不良事件报告的员工；或者
(4) Is a supervisor of these persons.	(4) 是这些人的主管。
(q) Nursing home means:	(q)疗养院 是指：
(1) An independent entity (i.e., not a part of a provider of services or	(1) 独立实体（即，不属于服务提供者或

any other facility) or one operated by another medical entity (e.g., under the common ownership, licensure, or control of an entity) that operates for the primary purpose of providing:	任何其他设施的一部分）或由另一医疗实体运营的实体（例如，在一个实体的共同所有权、许可或控制下）为主要经营提供的目的：
(i) Skilled nursing care and related services for persons who require medical or nursing care;	(i) 为需要医疗或护理的人提供专业护理和相关服务；
(ii) Hospice care to the terminally ill; or	(ii) 临终关怀；或者
(iii) Services for the rehabilitation of the injured, disabled, or sick.	(iii) 为伤者、残疾人或病人提供康复服务。
(2) A nursing home is subject to this regulation regardless of whether it is licensed by a Federal, State, municipal, or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the nursing home must report that event regardless of the nature or location of the medical service provided by the nursing home.	(2) 疗养院无论是否获得联邦、州、市或当地政府的许可，或者是否获得公认的认可机构的认可，均受本法规的约束。如果不良事件符合报告标准，疗养院必须报告该事件，无论疗养院提供的医疗服务的性质或地点如何。
(r) Outpatient diagnostic facility means:	(r)门诊诊断设施 是指：
(1) A distinct entity that:	(1) 一个独立的实体：
(i) Operates for the primary purpose of conducting medical diagnostic tests on patients,	(i) 主要目的是对患者进行医学诊断测试，
(ii) Does not assume ongoing responsibility for patient care, and	(ii) 不承担患者护理的持续责任，并且
(iii) Provides its services for use by other medical personnel.	(iii) 提供其服务供其他医务人员使用。
(2) Outpatient diagnostic facilities include outpatient facilities providing radiography, mammography, ultrasonography, electrocardiography, magnetic resonance imaging, computerized axial tomography, and in vitro testing. An outpatient diagnostic facility may be either independent (i.e., not a part of a provider of services or any other facility) or operated by another medical entity (e.g., under the common ownership, licensure, or control of an entity). An outpatient diagnostic facility is covered by this regulation regardless of whether it is licensed by a Federal, State, municipal, or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the outpatient diagnostic facility must report that event regardless of the nature or location of the medical service provided by the outpatient diagnostic facility.	(2) 门诊诊断设施包括提供射线照相、乳房X线照相术、超声检查、心电图、磁共振成像、计算机轴向断层扫描和体外测试的门诊设施。门诊诊断设施可以是独立的（即，不是服务提供者或任何其他设施的一部分）或由另一个医疗实体运营（例如，在一个实体的共同所有权、许可或控制下）。本法规涵盖门诊诊断设施，无论它是否获得联邦、州、市或地方政府的许可，或者是否获得认可的认证组织的认证。如果不良事件符合报告标准，
(s) Outpatient treatment facility means a distinct entity that operates for the primary purpose of providing nonsurgical therapeutic	(s)门诊治疗设施 指一个独立的实体，其主要目的是在门诊或家庭保健环境中提供

(medical, occupational, or physical) care on an outpatient basis or in a home health care setting. Outpatient treatment facilities include ambulance providers, rescue services, and home health care groups. Examples of services provided by outpatient treatment facilities include the following: Cardiac defibrillation, chemotherapy, radiotherapy, pain control, dialysis, speech or physical therapy, and treatment for substance abuse. An outpatient treatment facility may be either independent (i.e., not a part of a provider of services or any other facility) or operated by another medical entity (e.g., under the common ownership, licensure, or control of an entity). An outpatient treatment facility is covered by this regulation regardless of whether it is licensed by a Federal, State, municipal, or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the outpatient treatment facility must report that event regardless of the nature or location of the medical service provided by the outpatient treatment facility.	非手术治疗（医疗、职业或身体）护理。门诊治疗设施包括救护车提供者、救援服务和家庭保健团体。门诊治疗设施提供的服务示例如下：心脏除颤、化疗、放疗、疼痛控制、透析、言语或物理治疗，以及药物滥用治疗。门诊治疗设施可以是独立的（即，不是服务提供者或任何其他设施的一部分）或由另一个医疗实体运营（例如，在一个实体的共同所有权、许可或控制下）。本法规涵盖门诊治疗设施，无论它是否获得联邦、州、市或地方政府的许可，或者是否获得认可的认证机构的认证。如果不良事件符合报告标准，无论门诊治疗机构提供的医疗服务的性质或地点如何，门诊治疗机构都必须报告该事件。
(t) Patient of the facility means any individual who is being diagnosed or treated and/or receiving medical care at or under the control or authority of the facility. This includes employees of the facility or individuals affiliated with the facility who, in the course of their duties, suffer a device-related death or serious injury that has or may have been caused or contributed to by a device used at the facility.	(t)设施的患者是 指在设施或在设施的控制或授权下被诊断或治疗和/或接受医疗护理的任何个人。这包括设施的员工或与设施有关联的个人，他们在履行职责的过程中遭受了与设施相关的死亡或严重伤害，这些死亡或严重伤害已经或可能已经由设施使用的设备引起或促成。
(u) Physician's office means a facility that operates as the office of a physician or other health care professional for the primary purpose of examination, evaluation, and treatment or referral of patients. Examples of physician offices include: Dentist offices, chiropractor offices, optometrist offices, nurse practitioner offices, school nurse offices, school clinics, employee health clinics, or freestanding care units. A physician's office may be independent, a group practice, or part of a Health Maintenance Organization.	(u)医师办公室 是指作为医师或其他医疗保健专业人员办公室运作的设施，主要目的是检查、评估和治疗或转诊患者。医生办公室的例子包括：牙医办公室、脊医办公室、验光师办公室、执业护士办公室、学校护士办公室、学校诊所、员工健康诊所或独立护理单位。医师办公室可以是独立的、集体诊所或健康维护组织的一部分。
(v) Remedial action means any action other than routine maintenance or servicing of a device where such action is necessary to prevent recurrence of a reportable event.	(v)补救措施是指 除对设备进行日常维护或维修以外的任何措施，如果有必要采取此类措施来防止可报告事件的再次发生。
(w) Serious injury means an injury or illness that:	(w)严重伤害 是指以下伤害或疾病：

(1) Is life-threatening,	(1) 有生命危险，
(2) Results in permanent impairment of a body function or permanent damage to a body structure, or	(2) 导致身体功能永久性损伤或身体结构永久性损伤，或
(3) Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure. Permanent means irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage.	(3) 需要进行医疗或外科手术以防止身体功能的永久性损伤或身体结构的永久性损伤。永久性是指对身体结构或功能的不可逆转的损害或损害，不包括轻微的损害或损害。
(x) User facility report number means the number that uniquely identifies each report submitted by a user facility to manufacturers and to us. This number consists of the following three parts:	(x)用户设施报告编号 是指唯一标识用户设施提交给制造商和我们的每份报告的编号。这个数字由以下三部分组成：
(1) The user facility's 10-digit Centers for Medicare and Medicaid Services (CMS) number (if the CMS number has fewer than 10 digits, fill the remaining spaces with zeros);	(1) 用户设施的 10 位医疗保险和医疗补助服务中心 (CMS) 编号（如果 CMS 编号少于 10 位，则用零填充剩余空格）；
(2) The four-digit calendar year in which the report is submitted; and	(2) 提交报告的四位数日历年；和
(3) The four-digit sequence number of the reports submitted for the year, starting with 0001. (For example, a complete user facility report number will appear as follows: 1234560000-2011-0001. If a user facility has more than one CMS number, it must select one that will be used for all of its MDR reports. If a user facility has no CMS number, it should use all zeros in the appropriate space in its initial report (e.g., 0000000000-2011-0001). We will assign a number for future use and send that number to the user facility. This number is used in our record of the initial report, in subsequent reports, and in any correspondence with the user facility. If a facility has multiple sites, the primary site may submit reports for all sites and use one reporting number for all sites if the primary site provides the name, address, and CMS number for each respective site.)	(3) 当年提交的报告的四位序列号，从 0001 开始。（例如，完整的用户设施报告编号将显示如下：1234560000-2011-0001。如果用户设施有多个CMS 编号，它必须选择一个将用于其所有 MDR报告。如果用户设施没有 CMS 编号，它应该在其初始报告的适当空间中使用全零（例如，0000000000-2011-0001）。我们将分配一个编号以供将来使用，并将该编号发送给用户设施。此编号用于我们的初始报告记录、后续报告以及与用户设施的任何通信。如果设施有多个站点，则如果主要站点提供名称、地址、和每个站点的 CMS 编号。）
(y) Work day means Monday through Friday, except Federal holidays.	(y)工作日 是指周一至周五，联邦假日除外。
(z) [Reserved]	(z) [保留]
(aa) Human cell, tissue, or cellular or tissue-based product (HCT/P) regulated as a device means an HCT/P as defined in § 1271.3(d) of this chapter that does not meet the criteria in § 1271.10(a) and that is also regulated as a device.	(aa)作为器械监管的人体细胞、组织或基于细胞或组织的产品 (HCT/P) 是 指本章 § 1271.3(d) 定义的不符合 § 1271.10(a) 并且这也作为一种设备进行监管。
(bb) Unique device identifier (UDI) means an identifier that	(bb)唯一设备标识符 (UDI) 是指通过满足

adequately identifies a device through its distribution and use by meeting the requirements of § 830.20 of this chapter. A unique device identifier is composed of:	本章第 830.20 条的要求，通过其分发和使用充分识别设备的标识符。唯一的设备标识符 由以下部分组成：
(1) A device identifier - a mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device; and	(1)器械标识符 ——UDI 的强制性、固定部分，用于标识器械的特定版本或型号以及器械的标签；和
(2) A production identifier - a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device:	(2)生产标识符 - UDI 的一个有条件的可变部分，当包含在设备标签上时，它标识以下一项或多项：
(i) The lot or batch within which a device was manufactured;	(i) 制造设备的批次；
(ii) The serial number of a specific device;	(ii) 特定设备的序列号；
(iii) The expiration date of a specific device;	(iii) 特定设备的到期日期；
(iv) The date a specific device was manufactured.	(iv) 特定设备的制造日期。
(v) For an HCT/P regulated as a device, the distinct identification code required by § 1271.290(c) of this chapter.	(v) 对于作为设备监管的 HCT/P，本章第 1271.290(c) 节要求的独特识别码。
[79 FR 8846, Feb. 14, 2014, as amended at 80 FR 10587, Feb. 27, 2015]	[79 FR 8846，2014 年 2 月 14 日，经 80 FR 10587，2015 年 2 月 27 日修订]
§ 803.9 What information from the reports do we disclose to the public?	**§**803.9 我们向公众披露报告中的哪些信息？
(a) We may disclose to the public any report, including any FDA record of a telephone report, submitted under this part. Our disclosures are governed by part 20 of this chapter.	(a) 我们可以向公众披露根据本部分提交的任何报告，包括任何 FDA 的电话报告记录。我们的披露受本章第 20 部分的约束。
(b) Before we disclose a report to the public, we will delete the following:	(b) 在我们向公众披露报告之前，我们将删除以下内容：
(1) Any information that constitutes trade secret or confidential commercial or financial information under § 20.61 of this chapter;	(1) 构成本章第 20.61 条规定的商业秘密或机密商业或财务信息的任何信息；
(2) Any personal, medical, and similar information, including the serial number of implanted devices, which would constitute an invasion of personal privacy under § 20.63 of this chapter. However, if a patient requests a report, we will disclose to that patient all the information in the report concerning that patient, as provided in § 20.61 of this chapter; and	(2) 任何个人信息、医疗信息和类似信息，包括植入设备的序列号，根据本章第 20.63 条，这将构成对个人隐私的侵犯。但是，如果患者要求报告，我们将向该患者披露报告中有关该患者的所有信息，如本章第 20.61 节所述；和
(3) Any names and other identifying information of a third party that voluntarily submitted an adverse event report.	(3) 自愿提交不良事件报告的第三方的姓名等身份信息。
(c) We may not disclose the identity of a device user facility that makes a report under this part except in connection with:	(c) 我们不得披露根据本部分进行报告的设备用户设施的身份，除非与以下相关：

(1) An action brought to enforce section 301(q) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(q)), including the failure or refusal to furnish material or information required by section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i));	(1) 为执行《联邦食品、药品和化妆品法》（21 USC 331(q)）第 301(q) 节而提起的诉讼，包括未能或拒绝提供联邦食品第 519 节要求的材料或信息, 药品和化妆品法案 (21 USC 360i));
(2) A communication to a manufacturer of a device that is the subject of a report required to be submitted by a user facility under § 803.30; or	(2) 与设备制造商的通信，该设备是用户设施根据 § 803.30 要求提交的报告的主题；或者
(3) A disclosure to employees of the Department of Health and Human Services, to the Department of Justice, or to the duly authorized committees and subcommittees of the Congress.	(3) 向卫生与公众服务部的雇员、司法部或正式授权的国会委员会和小组委员会披露。
§ 803.10 Generally, what are the reporting requirements that apply to me?	**§**803.10 一般而言，适用于我的报告要求是什么？
(a) If you are a device user facility, you must submit reports (described in subpart C of this part), as follows:	(a) 如果您是设备用户设施，您必须提交报告（在本部分的 C 小节中描述），如下所示：
(1) Submit reports of individual adverse events no later than 10 work days after the day that you become aware of a reportable event:	(1) 在您得知可报告事件之日后的 10 个工作日内提交个别不良事件报告：
(i) Submit reports of device-related deaths to us and to the manufacturer, if known, or	(i) 向我们和制造商（如果已知）提交与设备相关的死亡报告，或
(ii) Submit reports of device-related serious injuries to the manufacturers or, if the manufacturer is unknown, submit reports to us.	(ii) 向制造商提交与设备相关的严重伤害报告，或者，如果制造商未知，则向我们提交报告。
(2) Submit annual reports (described in § 803.33) to us.	(2) 向我们提交年度报告（在 § 803.33 中描述）。
(b) If you are an importer, you must submit reports (described in subpart D of this part), as follows:	(b) 如果您是进口商，您必须提交报告（在本部分 D 小节中描述），如下所示：
(1) Submit reports of individual adverse events no later than 30 calendar days after the day that you become aware of a reportable event:	(1) 在您得知可报告事件之日后的 30 个日历日内提交个别不良事件报告：
(i) Submit reports of device-related deaths or serious injuries to us and to the manufacturer or	(i) 向我们和制造商提交与设备相关的死亡或重伤报告，或
(ii) Submit reports of device-related malfunctions to the manufacturer.	(ii) 向制造商提交与设备相关的故障报告。
(2) [Reserved]	(2) [保留]
(c) If you are a manufacturer, you must submit reports (described in	(c) 如果您是制造商，您必须向我们提交

subpart E of this part) to us, as follows:	报告（在本部分的 E 小节中描述），如下所示：
(1) Submit reports of individual adverse events no later than 30 calendar days after the day that you become aware of a reportable death, serious injury, or malfunction.	(1) 在您知道可报告的死亡、严重伤害或故障之日后的 30 个日历日内提交个别不良事件的报告。
(2) Submit reports of individual adverse events no later than 5 work days after the day that you become aware of:	(2) 在您知道以下情况之日后的 5 个工作日内提交个别不良事件报告：
(i) A reportable event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health or	(i) 需要采取补救措施以防止对公众健康造成重大损害的不合理风险的可报告事件，或
(ii) A reportable event for which we made a written request.	(ii) 我们提出书面请求的可报告事件。
(3) Submit supplemental reports if you obtain information that you did not submit in an initial report.	(3) 如果您获得了未在初次报告中提交的信息，请提交补充报告。
§ 803.11 What form should I use to submit reports of individual adverse events and where do I obtain these forms?	**§**803.11 我应该使用什么表格来提交个别不良事件的报告，我从哪里获得这些表格？
(a) If you are a manufacturer or importer, you must submit reports of individual adverse events to FDA in an electronic format in accordance with § 803.12(a) and § 803.20, unless granted an exemption under § 803.19.	(a) 如果您是制造商或进口商，您必须根据 § 803.12(a) 和 § 803.20 以电子格式向 FDA 提交个别不良事件报告，除非根据 § 803.19 获得豁免。
(b) Importer reports submitted to device manufacturers may be in paper format or an electronic format that includes all required data fields to ensure that the manufacturer has all required information.	(b) 提交给设备制造商的进口商报告可以是纸质格式或电子格式，包括所有必需的数据字段，以确保制造商拥有所有必需的信息。
(c) If you are a user facility, you must submit reports of individual adverse events in accordance with § 803.12(b) and § 803.20.	(c) 如果您是用户设施，您必须根据 § 803.12(b) 和 § 803.20 提交个别不良事件的报告。
(d) Form FDA 3500A is available on the internet at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm.	(d) 表格 FDA 3500A 可在互联网上获取，网址为 https://www.accessdata.fda.gov/scripts/medwatch/index.cfm。
[79 FR 8846, Feb. 14, 2014, as amended at 80 FR 10587, Feb. 27, 2015; 85 FR 18441, Apr. 2, 2020]	[79 FR 8846，2014 年 2 月 14 日，经 80 FR 10587，2015 年 2 月 27 日修订；85 FR 18441，2020 年 4 月 2 日]
§ 803.12 How do I submit initial and supplemental or followup reports?	**§**803.12 我如何提交初始和补充或后续报告？
(a) Manufacturers and importers must submit initial and	(a) 制造商和进口商必须以 FDA 可以处

supplemental or followup reports to FDA in an electronic format that FDA can process, review, and archive.	理、审查和存档的电子格式向 FDA 提交初始和补充或后续报告。
(b) User facilities that submit their reports and additional information to FDA electronically must use an electronic format that FDA can process, review, and archive. User facilities that submit their reports to FDA on paper must submit any written report or additional information required under this part to FDA, CDRH, Medical Device Reporting, P.O. Box 3002, Rockville, MD 20847-3002, using Form FDA 3500A. Each report must be identified (e.g., “User Facility Report” or “Annual Report”).	(b) 以电子方式向 FDA 提交报告和附加信息的用户设施必须使用 FDA 可以处理、审查和存档的电子格式。向 FDA 提交书面报告的用户设施必须使用 FDA 3500A 表格向 FDA、CDRH、医疗器械报告、邮政信箱 3002、Rockville、MD 20847-3002 提交本部分要求的任何书面报告或附加信息。必须确定每份报告（例如，“用户设施报告”或“年度报告”）。
(c) If you are confronted with a public health emergency, this can be brought to FDA's attention by contacting FDA's Office of Crisis Management, Emergency Operations Center by telephone, 24-hours a day, at 301-796-8240 or toll free at 866-300-4374, followed by the submission of an email to: emergency.operations@fda.hhs.gov.	(c) 如果您遇到突发公共卫生事件，可通过电话联系 FDA 危机管理办公室、紧急行动中心，电话301-796-8240 或免费电话 301-796-8240 866-300-4374，然后提交电子邮件至：emergency.operations@fda.hhs.gov。
Note: This action does not satisfy your obligation to report under part 803.	注： 这一行动不符合你根据第803部分提出报告的义务。
(d) You may submit a voluntary telephone report to the MedWatch office at 800-FDA-1088. You may also obtain information regarding voluntary reporting from the MedWatch office at 800-FDA-1088. You may also find the voluntary Form FDA 3500 and instructions to complete it at: http://www.fda.gov/Safety/ MedWatch/HowToReport/DownloadForms/default.htm.	(d) 您可以通过 800-FDA-1088 向 MedWatch 办公室提交自愿电话报告。您还可以通过 800-FDA-1088 从 MedWatch 办公室获取有关自愿报告的信息。您还可以在以下网址找到自愿填写的FDA 3500 表格和填写说明：http://www.fda.gov/Safety /MedWatch/HowToReport/DownloadForms/default.htm。
§ 803.13 Do I need to submit reports in English?	**§**803.13 我需要用英文提交报告吗？
Yes. You must submit all reports required by this part in English.	是的。您必须以英文提交本部分要求的所有报告。
§ 803.15 How will I know if you require more information about my medical device report?	**§**803.15 我如何知道您是否需要有关我的医疗器械报告的更多信息？
(a) We will notify you in writing if we require additional information and will tell you what information we need. We will require additional information if we determine that	(a) 如果我们需要更多信息，我们会以书面形式通知您，并告诉您我们需要哪些信息。如果我们确

protection of the public health requires additional or clarifying information for medical device reports submitted to us and in cases when the additional information is beyond the scope of FDA reporting forms or is not readily accessible to us.	定保护公众健康需要为提交给我们的医疗器械报告提供额外或澄清信息，并且如果额外信息超出FDA 报告表格的范围或我们无法轻松获取，我们将需要额外信息。
(b) In any request under this section, we will state the reason or purpose for the information request, specify the due date for submitting the information, and clearly identify the reported event(s) related to our request. If we verbally request additional information, we will confirm the request in writing.	(b) 在本节下的任何请求中，我们将说明信息请求的原因或目的，指定提交信息的截止日期，并明确标识与我们的请求相关的报告事件。如果我们口头要求提供更多信息，我们将以书面形式确认该要求。
§ 803.16 When I submit a report, does the information in my report constitute an admission that the device caused or contributed to the reportable event?	**§**803.16 当我提交报告时，我报告中的信息是否构成承认设备导致或促成了可报告事件？
No. A report or other information submitted by you, and our release of that report or information, is not necessarily an admission that the device, or you or your employees, caused or contributed to the reportable event. You do not have to admit and may deny that the report or information submitted under this part constitutes an admission that the device, you, or your employees, caused or contributed to a reportable event.	否。您提交的报告或其他信息，以及我们发布该报告或信息，并不一定承认该设备或您或您的员工导致或促成了可报告事件。您不必承认也可以否认根据本部分提交的报告或信息构成承认设备、您或您的员工导致或促成了可报告事件。
§ 803.17 What are the requirements for developing, maintaining, and implementing written MDR procedures that apply to me?	**§**803.17 开发、维护和实施适用于我的书面 MDR 程序有哪些要求？
If you are a user facility, importer, or manufacturer, you must develop, maintain, and implement written MDR procedures for the following:	如果您是用户设施、进口商或制造商，您必须针对以下内容制定、维护和实施书面 MDR 程序：
(a) Internal systems that provide for:	(a) 提供以下功能的内部系统：
(1) Timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements;	(1) 及时有效地识别、沟通和评估可能受到 MDR 要求的事件；
(2) A standardized review process or procedure for determining when an event meets the criteria for reporting under this part; and	(2) 用于确定事件何时符合本部分报告标准的标准化审查过程或程序；和
(3) Timely transmission of complete medical device reports to manufacturers or to us, or to both if required.	(3) 及时将完整的医疗器械报告传送给制造商或我们，或必要时传送给两者。
(b) Documentation and recordkeeping requirements for:	(b) 文件和记录保存要求：
(1) Information that was evaluated to determine if an event was reportable;	(1) 经评估以确定事件是否可报告的信息；
(2) All medical device reports and information submitted to manufacturers and/or us;	(2) 提交给制造商和/或我们的所有医疗器械报告和信息；

(3) Any information that was evaluated for the purpose of preparing the submission of annual reports; and	(3) 为准备提交年度报告而评估的任何信息；和
(4) Systems that ensure access to information that facilitates timely followup and inspection by us.	(4) 确保获取有助于我们及时跟进和检查的信息的系统。
§ 803.18 What are the requirements for establishing and maintaining MDR files or records that apply to me?	803.18 建立和维护适用于我的 MDR 文件或记录有哪些要求？
(a) If you are a user facility, importer, or manufacturer, you must establish and maintain MDR event files. You must clearly identify all MDR event files and maintain them to facilitate timely access.	(a) 如果您是用户设施、进口商或制造商，您必须建立和维护 MDR 事件文件。您必须清楚地识别所有 MDR 事件文件并维护它们以方便及时访问。
(b)	(b)
(1) For purposes of this part, “MDR event files” are written or electronic files maintained by user facilities, importers, and manufacturers. MDR event files may incorporate references to other information (e.g., medical records, patient files, engineering reports), in lieu of copying and maintaining duplicates in this file. Your MDR event files must contain:	(1) 就本部分而言，“MDR 事件文件”是由用户设施、进口商和制造商维护的书面或电子文件。MDR 事件文件可能包含对其他信息（例如，医疗记录、患者文件、工程报告）的引用，以代替在此文件中复制和维护副本。您的 MDR 事件文件必须包含：
(i) Information in your possession or references to information related to the adverse event, including all documentation of your deliberations and decision making processes used to determine if a device-related death, serious injury, or malfunction was or was not reportable under this part;	(i) 您拥有的信息或对与不良事件相关的信息的引用，包括您的审议和决策过程的所有文件，这些文件用于确定设备相关的死亡、严重伤害或故障是否根据本部分可报告；
(ii) Copies of all reports submitted under this part (whether paper or electronic), and of all other information related to the event that you submitted to us or other entities such as an importer, distributor, or manufacturer; and	(ii) 根据本部分提交的所有报告（无论是纸质的还是电子的）的副本，以及与您提交给我们或其他实体（例如进口商、分销商或制造商）的事件相关的所有其他信息的副本；和
(iii) Copies of all electronic acknowledgments FDA sends you in response to electronic MDR submissions.	(iii) FDA 为响应电子 MDR 提交而向您发送的所有电子确认的副本。
(2) If you are a user facility, importer, or manufacturer, you must permit any authorized FDA employee, at all reasonable times, to access, to copy, and to verify the records required by this part.	(2) 如果您是用户设施、进口商或制造商，您必须允许任何经授权的 FDA 员工在所有合理时间访问、复制和验证本部分要求的记录。
(c) If you are a user facility, you must retain an MDR event file relating to an adverse event for a period of 2 years from the date of the event. If you are a manufacturer or importer, you must retain an	(c) 如果您是用户设施，您必须保留与不良事件相关的 MDR 事件文件，期限为自事件发生之日起 2 年。如果您是制造商

MDR event file relating to an adverse event for a period of 2 years from the date of the event or a period of time equivalent to the expected life of the device, whichever is greater. If the device is no longer distributed, you still must maintain MDR event files for the time periods described in this paragraph (c).	或进口商，您必须保留与不良事件相关的 MDR 事件文件，期限为自事件发生之日起 2 年或相当于设备预期寿命的一段时间，以较大者为准。如果设备不再分发，您仍必须在本段 (c) 中描述的时间段内维护 MDR 事件文件。
(d)	(d)
(1) If you are a device distributor, you must establish and maintain device complaint records (files). Your records must contain any incident information, including any written, electronic, or oral communication, either received or generated by you, that alleges deficiencies related to the identity (e.g., labeling), quality, durability, reliability, safety, effectiveness, or performance of a device. You must also maintain information about your evaluation of the allegations, if any, in the incident record. You must clearly identify the records as device incident records and file these records by device name. You may maintain these records in written or electronic format. You must back up any file maintained in electronic format.	(1) 如果您是设备经销商，您必须建立和维护设备投诉记录（文件）。您的记录必须包含任何事件信息，包括您收到或生成的任何书面、电子或口头通信，这些信息声称与身份（例如标签）、质量、耐用性、可靠性、安全性、有效性或性能相关的缺陷的一个设备。您还必须在事件记录中保留有关您对指控的评估（如果有）的信息。您必须清楚地将这些记录标识为设备事件记录，并按设备名称归档这些记录。您可以以书面或电子格式保存这些记录。您必须备份以电子格式保存的任何文件。
(2) You must retain copies of the required device incident records for a period of 2 years from the date of inclusion of the record in the file or for a period of time equivalent to the expected life of the device, whichever is greater. You must maintain copies of these records for this period even if you no longer distribute the device.	(2) 您必须保留所需设备事故记录的副本，期限为自记录包含在文件中之日起 2 年或相当于设备预期寿命的期限，以较长者为准。即使您不再分发该设备，您也必须在此期间保留这些记录的副本。
(3) You must maintain the device complaint files established under this section at your principal business establishment. If you are also a manufacturer, you may maintain the file at the same location as you maintain your complaint file under part 820 of this chapter. You must permit any authorized FDA employee, at all reasonable times, to access, to copy, and to verify the records required by this part.	(3) 您必须在您的主要营业场所保存根据本节建立的设备投诉文件。如果您也是制造商，您可以根据本章第 820 部分将文件保存在与您保存投诉文件相同的位置。您必须允许任何经授权的 FDA 员工在所有合理时间访问、复制和验证本部分要求的记录。
(e) If you are a manufacturer, you may maintain MDR event files as part of your complaint file, under part 820 of this chapter, if you prominently identify these records as MDR reportable events. We will not consider your submitted MDR report to comply with this part unless you evaluate an event in accordance with the quality system	(e) 如果您是制造商，您可以根据本章第 820 部分将 MDR 事件文件作为投诉文件的一部分进行维护，前提是您将这些记录显着标识为 MDR 可报告事件。除非您根据本章第 820 部分中描述的质量体系要

requirements described in part 820 of this chapter. You must document and maintain in your MDR event files an explanation of why you did not submit or could not obtain any information required by this part, as well as the results of your evaluation of each event.	求评估事件，否则我们不会认为您提交的 MDR 报告符合本部分。您必须在您的 MDR 事件文件中记录和维护您未提交或无法获得本部分要求的任何信息的解释，以及您对每个事件的评估结果。
§ 803.19 Are there exemptions, variances, or alternative forms of adverse event reporting requirements?	803.19 是否有豁免、差异或替代形式的不良事件报告要求？
(a) We exempt the following persons from the adverse event reporting requirements in this part:	(a) 我们免除以下人员本部分的不良事件报告要求：
(1) A licensed practitioner who prescribes or administers devices intended for use in humans and manufactures or imports devices solely for use in diagnosing and treating persons with whom the practitioner has a “physician-patient” relationship;	(1) 开具或管理拟用于人类的器械并制造或进口仅用于诊断和治疗与其有“医患”关系的人的器械的执业医师；
(2) An individual who manufactures devices intended for use in humans solely for this person's use in research or teaching and not for sale. This includes any person who is subject to alternative reporting requirements under the investigational device exemption regulations (described in part 812 of this chapter), which require reporting of all adverse device effects; and	(2) 制造供人类使用的设备的个人，该设备仅用于该人的研究或教学用途，不得出售。这包括根据研究器械豁免条例（本章第 812 部分所述）需要报告所有不良器械影响的替代报告要求的任何人；和
(3) Dental laboratories or optical laboratories.	(3) 牙科实验室或光学实验室。
(b) If you are a manufacturer, importer, or user facility, you may request an exemption or variance from any or all of the reporting requirements in this part, including the requirements of § 803.12. You must submit the request to us in writing at the following address: MDR Exemption Requests, Medical Device Report (MDR) Team, Division of Regulatory Programs 3, Office of Regulatory Programs, Office of Product Evaluation and Quality, 10903 New Hampshire Ave., Bldg. 66, Rm.1523, Silver Spring, MD 20993-0002. Your request must include information necessary to identify you and the device; a complete statement of the request for exemption, variance, or alternative reporting; and an explanation why your request is justified. If you are requesting an exemption from the requirement to submit reports to FDA in electronic format under § 803.12(a), your request should indicate for how long you will require this exemption.	(b) 如果您是制造商、进口商或用户设施，您可以请求豁免或变更本部分中的任何或所有报告要求，包括 § 803.12 的要求。您必须在以下地址以书面形式向我们提交请求：MDR 豁免请求、医疗器械报告 (MDR) 团队、监管计划部 3、监管计划办公室、产品评估和质量办公室，10903 New Hampshire Ave., Bldg. 66, Rm.1523, Silver Spring, MD 20993-0002.您的请求必须包括识别您和设备所需的信息；豁免、差异或替代报告请求的完整声明；以及为什么您的请求是合理的解释。如果您要求免除根据 § 803.12(a) 以电子格式向 FDA 提交报告的要求，
(c) If you are a manufacturer, importer, or user facility, we may grant in writing an exemption or variance from, or alternative to, any or all of the reporting requirements in this part, and may change the	(c) 如果您是制造商、进口商或用户设施，我们可以书面形式授予对本部分中任何或所有报告要求的豁免、变更或替代，

frequency of reporting to quarterly, semiannually, annually or other appropriate time period. We may grant these modifications in response to your request, as described in paragraph (b) of this section, or at our discretion. When we grant modifications to the reporting requirements, we may impose other reporting requirements to ensure the protection of public health.	并且可以将报告频率更改为季度报告、每半年、每年或其他适当的时间段。如本节 (b) 段所述，我们可能会根据您的请求或自行决定授予这些修改。当我们批准修改报告要求时，我们可能会施加其他报告要求以确保保护公众健康。
(d) We may revoke or modify in writing an exemption, variance, or alternative reporting requirement if we determine that revocation or modification is necessary to protect the public health.	(d) 如果我们确定有必要撤销或修改以保护公众健康，我们可能会以书面形式撤销或修改豁免、差异或替代报告要求。
(e) If we grant your request for a reporting modification, you must submit any reports or information required in our approval of the modification. The conditions of the approval will replace and supersede the regular reporting requirement specified in this part until such time that we revoke or modify the alternative reporting requirements in accordance with paragraph (d) of this section or until the date specified in our response granting your variance, at which time the provisions of this part will again apply.	(e) 如果我们批准您的报告修改请求，您必须提交我们批准修改所需的任何报告或信息。批准条件将取代和取代本部分规定的定期报告要求，直到我们根据本节 (d) 段撤销或修改替代报告要求，或直到我们的答复中指定的日期，同意您的差异，届时本部分的规定将再次适用。
[79 FR 8846, Feb. 14, 2014, as amended at 85 FR 18441, Apr. 2, 2020]	[79 FR 8846，2014 年 2 月 14 日，经 85 FR 18441，2020 年 4 月 2 日修订]
Subpart B - Generally Applicable Requirements for Individual Adverse Event Reports	**B** 子部分 **-** 个别不良事件报告的一般适用要求
§ 803.20 How do I complete and submit an individual adverse event report?	**§**803.20 我如何填写和提交个人不良事件报告？
(a) What form must I complete and submit ?	(a)我必须填写并提交什么表格？
(1) If you are a health professional or consumer or other entity, you may submit voluntary reports to FDA regarding devices or other FDA-regulated products using the Form FDA 3500.	(1) 如果您是卫生专业人员或消费者或其他实体，您可以使用 FDA 3500 表格向 FDA 提交有关设备或其他 FDA 监管产品的自愿报告。
(2) To submit a mandatory report in written form, a user facility must use Form FDA 3500A.	(2) 要以书面形式提交强制性报告，用户设施必须使用 FDA 3500A 表格。
(3) An electronic submission of a mandatory report from a user facility, importer, or manufacturer must contain the information from the applicable blocks of Form FDA 3500A. All electronic submissions must include information about the patient, the event, the device, and the “initial reporter.” An electronic submission from a user facility or importer must include the information from block F. An electronic submission from a manufacturer must include the information from	(3) 用户设施、进口商或制造商以电子方式提交的强制性报告必须包含来自 FDA 3500A 表格适用部分的信息。所有电子提交都必须包括有关患者、事件、设备和“初始报告人”的信息。来自用户设施或进口商的电子提交必须包括来自 F 块的信息。来自制造商的电子提交必须包括来自

blocks G and H. If you are a manufacturer and you receive a report from a user facility or importer, you must incorporate that information in your electronic submission and include any corrected or missing information.	G 块和 H 块的信息。如果您是制造商并且您收到来自用户设施或进口商的报告，您必须将该信息包含在您的电子提交中，并包括任何更正或缺失的信息。
(b) To whom must I submit reports and when ?	(b)我必须向谁提交报告以及何时提交？
(1) If you are a user facility, you must submit MDR reports to:	(1) 如果您是用户设施，您必须将 MDR 报告提交给：
(i) The manufacturer and to us no later than 10 work days after the day that you become aware of information that reasonably suggests that a device has or may have caused or contributed to a death or	(i) 制造商和我们不迟于您知道合理暗示设备已经或可能已经导致或促成死亡的信息之日后的 10 个工作日，或
(ii) The manufacturer no later than 10 work days after the day that you become aware of information that reasonably suggests that a device has or may have caused or contributed to a serious injury. If the manufacturer is not known, you must submit this report to us.	(ii) 制造商不迟于您得知有合理信息表明设备已经或可能已经造成或促成了严重伤害之日后的 10 个工作日。如果制造商未知，您必须将此报告提交给我们。
(2) If you are an importer, you must submit MDR reports to:	(2) 如果您是进口商，您必须将 MDR 报告提交至：
(i) The manufacturer and to us, no later than 30 calendar days after the day that you become aware of information that reasonably suggests that a device has or may have caused or contributed to a death or serious injury or	(i) 制造商和我们，不迟于您知道合理暗示设备已经或可能已经导致或促成死亡或严重伤害的信息之日后的 30 个日历日，或
(ii) The manufacturer, no later than 30 calendar days after receiving information that a device you market has malfunctioned and that this device or a similar device that you market would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.	(ii) 制造商在收到有关您销售的设备发生故障并且您销售的该设备或类似设备可能会导致或导致死亡或严重伤害的信息后的 30 个日历日内，如果故障是复发。
(3) If you are a manufacturer, you must submit MDR reports to us:	(3) 如果您是制造商，您必须向我们提交 MDR 报告：
(i) No later than 30 calendar days after the day that you become aware of information that reasonably suggests that a device may have caused or contributed to a death or serious injury or	(i) 不迟于您得知有合理信息表明设备可能已导致或促成死亡或重伤或
(ii) No later than 30 calendar days after the day that you become aware of information that reasonably suggests a device has malfunctioned and that this device or a similar device that you market would be likely to cause or contribute to a death or serious injury if the malfunction were to recur; or	(ii) 不迟于您得知有合理信息表明设备出现故障并且您销售的该设备或类似设备可能会导致或促成死亡或严重伤害的信息之日起 30 个日历日内，如果故障将再次发生；或者
(iii) Within 5 work days if required by § 803.53.	(iii) 如果第 803.53 条要求，在 5 个工作日内。

(c) What kind of information reasonably suggests that a reportable event has occurred?	(c)什么样的信息合理地表明发生了应报告事件？
(1) Any information, including professional, scientific, or medical facts, observations, or opinions, may reasonably suggest that a device has caused or may have caused or contributed to an MDR reportable event. An MDR reportable event is a death, a serious injury, or, if you are a manufacturer or importer, a malfunction that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.	(1) 任何信息，包括专业、科学或医学事实、观察或意见，都可能合理地表明设备已经或可能已经导致或促成了 MDR 可报告事件。MDR 可报告事件是死亡、重伤，或者，如果您是制造商或进口商，如果故障再次发生，可能会导致或促成死亡或重伤的故障。
(2) If you are a user facility, importer, or manufacturer, you do not have to report an adverse event if you have information that would lead a person who is qualified to make a medical judgment reasonably to conclude that a device did not cause or contribute to a death or serious injury, or that a malfunction would not be likely to cause or contribute to a death or serious injury if it were to recur. Persons qualified to make a medical judgment include physicians, nurses, risk managers, and biomedical engineers. You must keep in your MDR event files (described in § 803.18) the information that the qualified person used to determine whether or not a device-related event was reportable.	(2) 如果您是用户设施、进口商或制造商，如果您掌握的信息会导致有资格做出医疗判断的人合理地断定设备没有导致或导致死亡或严重伤害，或者故障如果再次发生不会导致或促成死亡或严重伤害。有资格做出医疗判断的人员包括医生、护士、风险管理人员和生物医学工程师。您必须将合格人员用于确定设备相关事件是否可报告的信息保存在您的 MDR 事件文件（在 § 803.18 中描述）中。
§ 803.21 Where can I find the reporting codes for adverse events that I use with medical device reports?	**§**803.21 在哪里可以找到用于医疗器械报告的不良事件报告代码？
(a) The MedWatch Medical Device Reporting Code Instruction Manual contains adverse event codes for use with Form FDA 3500A. You may obtain the coding manual from FDA's website at: https://www.fda.gov/medical-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities/mdr-adverse-event-codes.	(a) MedWatch 医疗器械报告代码说明手册包含与表格 FDA 3500A 一起使用的不良事件代码。您可以从 FDA 的网站获取编码手册https ://www.fda.gov/medical-devices/mandatory reporting-requirements-manufacturers-importers-and-device-user facilities/mdr-adverse-event-codes .
(b) We may sometimes use additional coding of information on the reporting forms or modify the existing codes. If we do make modifications, we will ensure that we make the new coding information available to all reporters.	(b) 我们有时可能会在报告表格上使用额外的信息编码或修改现有编码。如果我们确实进行了修改，我们将确保我们向所有记者提供新的编码信息。
[79 FR 8846, Feb. 14, 2014, as amended at 85 FR 18441, Apr. 2, 2020]	[79 FR 8846，2014 年 2 月 14 日，经 85 FR 18441，2020 年 4 月 2 日修订]
§ 803.22 What are the circumstances in which I am not required	**§**803.22 什么情况下不需要我提交报告？

to file a report?	
(a) If you become aware of information from multiple sources regarding the same patient and same reportable event, you may submit one medical device report.	(a) 如果您从多个来源了解到有关同一患者和同一可报告事件的信息，您可以提交一份医疗器械报告。
(b) You are not required to submit a medical device report if:	(b) 在以下情况下，您无需提交医疗器械报告：
(1) You are a user facility, importer, or manufacturer, and you determine that the information received is erroneous in that a device-related adverse event did not occur. You must retain documentation of these reports in your MDR files for the time periods specified in § 803.18.	(1) 您是用户设施、进口商或制造商，并且您确定收到的信息是错误的，因为没有发生与设备相关的不良事件。您必须在第 803.18 节中指定的时间段内将这些报告的文档保留在您的 MDR 文件中。
(2) You are a manufacturer or importer and you did not manufacture or import the device about which you have adverse event information. When you receive reportable event information in error, you must forward this information to us with a cover letter explaining that you did not manufacture or import the device in question.	(2) 您是制造商或进口商，并且您没有制造或进口您拥有不良事件信息的设备。当您收到错误的可报告事件信息时，您必须将此信息连同一封说明您没有制造或进口相关设备的求职信转发给我们。
§ 803.23 Where can I find information on how to prepare and submit an MDR in electronic format?	**§**803.23 我在哪里可以找到有关如何准备和提交电子格式的 MDR 的信息？
(a) You may obtain information on how to prepare and submit reports in an electronic format that FDA can process, review, and archive at: http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107903.htm.	(a) 您可以在以下网址获取有关如何以 FDA 可以处理、审查和存档的电子格式准备和提交报告的信息：http ://www.fda.gov/ForIndustry /FDAeSubmitter/ucm107903.htm 。
(b) We may sometimes update information on how to prepare and submit reports electronically. If we do make modifications, we will ensure that we alert reporters by updating the eMDR Web page.	(b) 我们有时可能会更新有关如何以电子方式准备和提交报告的信息。如果我们确实进行了修改，我们将确保通过更新 eMDR 网页来提醒记者。
Subpart C - User Facility Reporting Requirements	**C**子部分 **-** 用户设施报告要求
§ 803.30 If I am a user facility, what reporting requirements apply to me?	**§**803.30 如果我是用户设施，哪些报告要求适用于我？
(a) You must submit reports to the manufacturer or to us, or both, as specified in paragraphs (a)(1) and (a)(2) of this section as follows:	(a) 您必须按照本节 (a)(1) 和 (a)(2) 段的规定向制造商或我们或两者提交报告，具体如下：
(1) Reports of death. You must submit a report to us as soon as practicable but no more than 10 work days after the day that you become aware of information, from any source, that reasonably suggests that a device has or may have caused or contributed to the	(1)死亡报告。 您必须在切实可行的范围内尽快向我们提交报告，但不得超过在您从任何来源获悉信息之日起的 10 个工作日内，这些信息合理地表明设备已经或可

death of a patient of your facility. You must also submit the report to the device manufacturer, if known. You must submit the information required by § 803.32. Reports sent to the Agency must be submitted in accordance with the requirements of § 803.12(b).	能已经导致或促成了一个人的死亡。您所在机构的患者。如果已知，您还必须将报告提交给设备制造商。您必须提交第 803.32 条要求的信息。发送给机构的报告必须按照 § 803.12(b) 的要求提交。
(2) Reports of serious injury. You must submit a report to the manufacturer of the device no later than 10 work days after the day that you become aware of information, from any source, that reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient of your facility. If the manufacturer is not known, you must submit the report to us. You must report information required by § 803.32. Reports sent to the Agency must be submitted in accordance with the requirements of § 803.12 (b).	(2)重伤报告。 您必须在您从任何来源获悉信息合理地表明设备已经或可能已经造成或促成了严重伤害的信息后的 10 个工作日内向设备制造商提交报告您所在机构的患者。如果制造商未知，您必须向我们提交报告。您必须报告第 803.32 条要求的信息。发送给机构的报告必须按照 § 803.12 (b) 的要求提交。
(b) What information does FDA consider “reasonably known” to me? You must submit all information required in this subpart C that is reasonably known to you. This information includes information found in documents that you possess and any information that becomes available as a result of reasonable followup within your facility. You are not required to evaluate or investigate the event by obtaining or evaluating information that you do not reasonably know.	(b) FDA 认为我“合理知道”哪些信息？ 您必须提交本子部分 C 中要求的所有您合理知道的信息。此信息包括在您拥有的文件中找到的信息，以及在您的设施内进行合理跟进而获得的任何信息。您无需通过获取或评估您不合理知道的信息来评估或调查事件。
§ 803.32 If I am a user facility, what information must I submit in my individual adverse event reports?	803.32 如果我是用户设施，我必须在我的个人不良事件报告中提交哪些信息？
You must include the following information in your report, if reasonably known to you, as described in § 803.30(b). These types of information correspond generally to the elements of Form FDA 3500A:	如 § 803.30(b) 所述，如果您合理地知道，您必须在报告中包含以下信息。这些类型的信息通常对应于表格 FDA 3500A 的元素：
(a) Patient information (Form FDA 3500A, Block A). You must submit the following:	(a) 患者信息（表格 FDA 3500A，A 块）。您必须提交以下内容：
(1) Patient name or other identifier; (2) Patient age at the time of event, or date of birth; (3) Patient gender; and (4) Patient weight.	(1) 患者姓名或其他标识； (2) 事件发生时的患者年龄或出生日期； (3) 患者性别；和 (4) 患者体重。
(b) Adverse event or product problem (Form FDA 3500A, Block B). You must submit the following:	(b) 不良事件或产品问题（表格 FDA 3500A，B 块）。您必须提交以下内容：
(1) Identification of adverse event or product problem;	(1) 不良事件或产品问题的识别；
(2) Outcomes attributed to the adverse event (e.g., death or serious	(2) 归因于不良事件的结果（例如，死亡

injury). An outcome is considered a serious injury if it is:	或重伤）。如果结果是以下情况，则将其视为严重伤害：
(i) A life-threatening injury or illness; (ii) A disability resulting in permanent impairment of a body function or permanent damage to a body structure; or (iii) An injury or illness that requires intervention to prevent permanent impairment of a body structure or function;	(i) 危及生命的伤害或疾病； (ii) 导致身体功能永久性损伤或身体结构永久性损伤的残疾；或者 (iii) 需要干预以防止对身体结构或功能造成永久性损害的伤害或疾病；
(3) Date of event;	(3) 事件发生日期；
(4) Date of this report;	(4)本报告日期；
(5) Description of event or problem, including a discussion of how the device was involved, nature of the problem, patient followup or required treatment, and any environmental conditions that may have influenced the event;	(5) 事件或问题的描述，包括对设备如何参与、问题的性质、患者随访或所需治疗以及可能影响事件的任何环境条件的讨论；
(6) Description of relevant tests, including dates and laboratory data; and	(6) 相关测试的描述，包括日期和实验室数据；和
(7) Description of other relevant history, including preexisting medical conditions.	(7) 其他相关病史的描述，包括先前存在的医疗状况。
(c) Device information (Form FDA 3500A, Block D). You must submit the following:	(c) 设备信息（表格 FDA 3500A，块 D）。您必须提交以下内容：
(1) Brand name; (2) Product Code, if known, and Common Device Name; (3) Manufacturer name, city, and state; (4) Model number, catalog number, serial number, lot number, or other identifying number; expiration date; and unique device identifier (UDI) that appears on the device label or on the device package; (5) Operator of the device (health professional, lay user/patient, other); (6) Date of device implantation (month, day, year), if applicable; (7) Date of device explantation (month, day, year), if applicable; (8) Whether the device is a single-use device that was reprocessed and reused on a patient (Yes, No)? (9) If the device is a single-use device that was reprocessed and reused on a patient (yes to paragraph (c)(8) of this section), the name and address of the reprocessor; (10) Whether the device was available for evaluation and whether the device was returned to the manufacturer; if so, the date it was	(1) 品牌名称； (2) 产品代码（如果知道）和通用设备名称； (3) 制造商名称、城市和州； (4) 型号、目录号、序列号、批号或其他识别号；截止日期; 以及出现在设备标签或设备包装上的唯一设备标识符 (UDI)； (5) 设备操作者（卫生专业人员、非专业用户/患者、其他）； (6) 器械植入日期（月、日、年），如适用； (7) 器械移植日期（月、日、年），如适用； (8) 该器械是否是在患者身上再加工和重复使用的一次性器械（是，否）？ (9) 如果设备是在患者身上再处理和再利用的一次性设备（本节第 (c)(8) 段是），再处理者的名称和地址；

returned to the manufacturer; and (11) Concomitant medical products and therapy dates. (Do not report products that were used to treat the event.)	(10) 设备是否可供评估，设备是否退回制造商；如果是，则返回制造商的日期；和 (11) 伴随的医疗产品和治疗日期。（不要报告用于治疗事件的产品。）
(d) Initial reporter information (Form FDA 3500A, Block E). You must submit the following:	(d) 初始报告人信息（表格 FDA 3500A，E 块）。您必须提交以下内容：
(1) Name, address, and telephone number of the reporter who initially provided information to you, or to the manufacturer or distributor; (2) Whether the initial reporter is a health professional; (3) Occupation; and (4) Whether the initial reporter also sent a copy of the report to us, if known.	(1) 最初向您或制造商或经销商提供信息的举报人的姓名、地址和电话号码； (2) 初始报告人是否为卫生专业人员； (3) 职业；和 (4) 初始报告人是否也向我们发送了一份报告副本，如果知道的话。
(e) User facility information (Form FDA 3500A, Block F). You must submit the following:	(e) 用户设施信息（表格 FDA 3500A，F 块）。您必须提交以下内容：
(1) An indication that this is a user facility report (by marking the user facility box on the form); (2) Your user facility number; (3) Your address; (4) Your contact person; (5) Your contact person's telephone number; (6) Date that you became aware of the event (month, day, year); (7) Type of report (initial or followup); if it is a followup, you must include the report number of the initial report; (8) Date of your report (month, day, year); (9) Approximate age of device; (10) Event problem codes - patient code and device code (refer to the “MedWatch Medical Device Reporting Code Instructions”); (11) Whether a report was sent to us and the date it was sent (month, day, year); (12) Location where the event occurred; (13) Whether the report was sent to the manufacturer and the date it was sent (month, day, year); and (14) Manufacturer name and address, if available.	(1) 表明这是一份用户设施报告（通过在表格上标记用户设施框）； (2) 您的用户设施号； (3) 您的地址； (4) 您的联系人； (5) 您的联系人的电话号码； (6) 您知道该事件的日期（月、日、年）； (7) 报告类型（初始或后续）；如果是跟进，您必须包括初始报告的报告编号； (8) 报告日期（月、日、年）； (9) 设备的大概使用年限； (10) 事件问题代码——患者代码和器械代码（参考《MedWatch医疗器械报告代码说明》）； (11) 是否向我们发送了报告以及发送日期（月、日、年）； (12) 事件发生地点； (13) 报告是否送达制造商及送达日期（月、日、年）；和 (14) 制造商名称和地址（如果有）。

[79 FR 8846, Feb. 14, 2014, as amended at 80 FR 10587, Feb. 27, 2015]	[79 FR 8846，2014 年 2 月 14 日，经 80 FR 10587，2015 年 2 月 27 日修订]
§ 803.33 If I am a user facility, what must I include when I submit an annual report?	§803.33 如果我是用户设施，我在提交年度报告时必须包括什么？
(a) You must submit to us an annual report on Form FDA 3419. You must submit an annual report by January 1, of each year. You may obtain this form on the internet at: https://www.fda.gov/media/72292/download.	(a) 您必须向我们提交一份关于表格 FDA 3419 的年度报告。您必须在每年的 1 月 1 日之前提交一份年度报告。您可以在互联网上获取此表格：https://www.fda.gov/media/72292/download。
(b) You must clearly identify your annual report as such. You must submit your annual report to FDA, CDRH, Medical Device Reporting, P.O. Box 3002, Rockville, MD 20847-3002. Your annual report must include:	(b) 您必须清楚地标明您的年度报告。您必须向 FDA、CDRH、Medical Device Reporting、P.O.Box 3002, Rockville, MD 20847-3002 提交您的年度报告。您的年度报告必须包括：
(1) Your CMS provider number used for medical device reports, or the number assigned by us for reporting purposes in accordance with § 803.3; (2) Reporting year; (3) Your name and complete address; (4) Total number of reports attached or summarized; (5) Date of the annual report and report numbers identifying the range of medical device reports that you submitted during the report period (e.g., 1234567890-2011-0001 through 1000); (6) Name, position title, and complete address of the individual designated as your contact person responsible for reporting to us and whether that person is a new contact for you; and	(1) 您用于医疗器械报告的 CMS 提供商编号，或我们根据 § 803.3 为报告目的分配的编号； (2) 报告年度； (3) 您的姓名和完整地址； (4) 附上或汇总的报告总数； (5) 年度报告日期和报告编号，识别您在报告期内提交的医疗器械报告范围（例如，1234567890-2011-0001 至 1000）； (6) 指定为您负责向我们报告的联系人的姓名、职位和完整地址，以及该人是否是您的新联系人；和
(7) Information for each reportable event that occurred during the annual reporting period including:	(7) 年度报告期内发生的各项应报告事项的信息，包括：
(i) Report number; (ii) Name and address of the device manufacturer; (iii) Device brand name and common name; (iv) Product model, catalog, serial, and lot number and unique device identifier (UDI) that appears on the device label or on the device package; (v) A brief description of the event reported to the manufacturer	(i) 报告编号； (ii) 设备制造商的名称和地址； (iii) 器械品牌名称和通用名称； (iv) 出现在设备标签或设备包装上的产品型号、目录、序列号和批号以及唯一设备标识符(UDI)； (v) 向制造商和/或我们报告的事件的简要

and/or us; and (vi) Where the report was submitted, i.e., to the manufacturer, importer, or us.	说明；和 (vi) 报告提交的地点，即制造商、进口商或我们。
(c) In lieu of submitting the information in paragraph (b)(7) of this section, you may submit a copy of each medical device report that you submitted to the manufacturers and/or to us during the reporting period.	(c) 代替提交本节 (b)(7) 段中的信息，您可以提交您在报告期内提交给制造商和/或我们的每份医疗器械报告的副本。
(d) If you did not submit any medical device reports to manufacturers or us during the time period, you do not need to submit an annual report.	(d) 如果您在此期间未向制造商或我们提交任何医疗器械报告，则无需提交年度报告。
[79 FR 8846, Feb. 14, 2014, as amended at 80 FR 10587, Feb. 27, 2015; 85 FR 18442, Apr. 2, 2020]	[79 FR 8846，2014 年 2 月 14 日，经 80 FR 10587，2015 年 2 月 27 日修订；85 FR 18442，2020 年 4 月 2 日]
Subpart D - Importer Reporting Requirements	**D** 子部分 **-** 进口商报告要求
§ 803.40 If I am an importer, what reporting requirements apply to me?	**§**803.40 如果我是进口商，有哪些报告要求适用于我？
(a) Reports of deaths or serious injuries. You must submit a report to us, and a copy of this report to the manufacturer, as soon as practicable, but no later than 30 calendar days after the day that you receive or otherwise become aware of information from any source, including user facilities, individuals, or medical or scientific literature, whether published or unpublished, that reasonably suggests that one of your marketed devices may have caused or contributed to a death or serious injury. You must submit the information required by § 803.42. Reports sent to the Agency must be submitted in accordance with the requirements of § 803.12(a).	(a)死亡或重伤报告。 您必须尽快向我们提交报告，并将该报告的副本提交给制造商，但不得迟于您收到或以其他方式获知来自任何来源（包括用户设施）的信息之日后的 30 个日历日，个人，或医学或科学文献，无论已发表或未发表，合理地表明您的销售设备之一可能已导致或促成死亡或严重伤害。您必须提交第 803.42 条要求的信息。发送给机构的报告必须按照 § 803.12(a) 的要求提交。
(b) Reports of malfunctions. You must submit a report to the manufacturer as soon as practicable but no later than 30 calendar days after the day that you receive or otherwise become aware of information from any source, including user facilities, individuals, or through your own research, testing, evaluation, servicing, or maintenance of one of your devices, that reasonably suggests that one of your devices has malfunctioned and that this device or a similar device that you market would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. You must submit the information required by § 803.42. Reports to manufacturers may be made in accordance with § 803.11(b).	(b)故障报告。 您必须尽快向制造商提交报告，但不得迟于您收到或以其他方式获知来自任何来源（包括用户设施、个人或通过您自己的研究、测试、评估）的信息之日后的 30 个日历日、维修或维护您的一台设备，合理地表明您的一台设备发生故障，并且如果故障发生，该设备或您销售的类似设备可能会导致或导致死亡或重伤复发。您必须提交第 803.42 条要求的信息。可以根据 § 803.11(b) 向制造商报告。

§ 803.42 If I am an importer, what information must I submit in my individual adverse event reports?	**§**803.42 如果我是进口商，我必须在个人不良事件报告中提交哪些信息？
You must include the following information in your report, if the information is known or should be known to you, as described in § 803.40. These types of information correspond generally to the format of Form FDA 3500A:	如果您知道或应该知道以下信息，您必须在报告中包含以下信息，如 § 803.40 中所述。这些类型的信息通常对应于表格 FDA 3500A 的格式：
(a) Patient information (Form FDA 3500A, Block A). You must submit the following:	(a) 患者信息（表格 FDA 3500A，A 块）。您必须提交以下内容：
(1) Patient name or other identifier; (2) Patient age at the time of event, or date of birth; (3) Patient gender; and (4) Patient weight.	(1) 患者姓名或其他标识； (2) 事件发生时的患者年龄或出生日期； (3) 患者性别；和 (4) 患者体重。
(b) Adverse event or product problem (Form FDA 3500A, Block B). You must submit the following:	(b) 不良事件或产品问题（表格 FDA 3500A，B 块）。您必须提交以下内容：
(1) Identification of adverse event or product problem;	(1) 不良事件或产品问题的识别；
(2) Outcomes attributed to the adverse event (e.g., death or serious injury). An outcome is considered a serious injury if it is:	(2) 归因于不良事件的结果（例如，死亡或重伤）。如果结果是以下情况，则将其视为严重伤害：
(i) A life-threatening injury or illness; (ii) A disability resulting in permanent impairment of a body function or permanent damage to a body structure; or (iii) An injury or illness that requires intervention to prevent permanent impairment of a body structure or function;	(i) 危及生命的伤害或疾病； (ii) 导致身体功能永久性损伤或身体结构永久性损伤的残疾；或者 (iii) 需要干预以防止对身体结构或功能造成永久性损害的伤害或疾病；
(3) Date of event; (4) Date of this report; (5) Description of the event or problem, including a discussion of how the device was involved, nature of the problem, patient followup or required treatment, and any environmental conditions that may have influenced the event; (6) Description of relevant tests, including dates and laboratory data; and (7) Description of other relevant patient history, including preexisting medical conditions.	(3) 事件发生日期； (4) 本报告日期； (5) 事件或问题的描述，包括对设备如何参与、问题的性质、患者随访或所需治疗以及可能影响事件的任何环境条件的讨论； (6) 相关测试的描述，包括日期和实验室数据；和 (7) 其他相关患者病史的描述，包括先前存在的医疗状况。
(c) Device information (Form FDA 3500A, Block D). You must submit the following:	(c) 设备信息（表格 FDA 3500A，块 D）。您必须提交以下内容：
(1) Brand name; (2) Product Code, if known, and Common Device Name;	(1) 品牌名称； (2) 产品代码（如果知道）和通用设备名

(3) Manufacturer name, city, and state; (4) Model number, catalog number, serial number, lot number, or other identifying number; expiration date; and unique device identifier (UDI) that appears on the device label or on the device package; (5) Operator of the device (health professional, lay user/patient, other); (6) Date of device implantation (month, day, year), if applicable; (7) Date of device explanation (month, day, year), if applicable; (8) Whether the device is a single-use device that was reprocessed and reused on a patient (Yes, No)? (9) If the device is a single-use device that was reprocessed and reused on a patient (yes to paragraph (c)(8) of this section), the name and address of the reprocessor; (10) Whether the device was available for evaluation, and whether the device was returned to the manufacturer, and if so, the date it was returned to the manufacturer; and (11) Concomitant medical products and therapy dates. (Do not report products that were used to treat the event.)	称； (3) 制造商名称、城市和州； (4) 型号、目录号、序列号、批号或其他识别号；截止日期; 以及出现在设备标签或设备包装上的唯一设备标识符 (UDI)； (5) 设备操作者（卫生专业人员、非专业用户/患者、其他）； (6) 器械植入日期（月、日、年），如适用； (7) 器械解释日期（月、日、年），如适用； (8) 该器械是否是在患者身上再加工和重复使用的一次性器械（是，否）？ (9) 如果设备是在患者身上再处理和再利用的一次性设备（本节第 (c)(8) 段是），再处理者的名称和地址； (10) 设备是否可供评估，是否返回制造商，如果是，返回制造商的日期；和 (11) 伴随的医疗产品和治疗日期。（不要报告用于治疗事件的产品。）
(d) Initial reporter information (Form FDA 3500A, Block E). You must submit the following:	(d) 初始报告人信息（表格 FDA 3500A，E 块）。您必须提交以下内容：
(1) Name, address, and telephone number of the reporter who initially provided information to the manufacturer, user facility, or distributor; (2) Whether the initial reporter is a health professional; (3) Occupation; and (4) Whether the initial reporter also sent a copy of the report to us, if known.	(1) 最初向制造商、用户设施或分销商提供信息的报告者的姓名、地址和电话号码； (2) 初始报告人是否为卫生专业人员； (3) 职业；和 (4) 初始报告人是否也向我们发送了一份报告副本，如果知道的话。
(e) Importer information (Form FDA 3500A, Block F). You must submit the following:	(e) 进口商信息（表格 FDA 3500A，F 块）。您必须提交以下内容：
(1) An indication that this is an importer report (by marking the importer box on the form); (2) Your importer report number; (3) Your address; (4) Your contact person; (5) Your contact person's telephone number;	(1) 表明这是一份进口商报告（通过在表格上标记进口商框）； (2) 您的进口商报告编号； (3) 您的地址； (4) 您的联系人； (5) 您的联系人的电话号码；

(6) Date that you became aware of the event (month, day, year); (7) Type of report (initial or followup). If it is a followup report, you must include the report number of your initial report; (8) Date of your report (month, day, year); (9) Approximate age of device; (10) Event problem codes - patient code and device code (refer to FDA MedWatch Medical Device Reporting Code Instructions); (11) Whether a report was sent to us and the date it was sent (month, day, year); (12) Location where event occurred; (13) Whether a report was sent to the manufacturer and the date it was sent (month, day, year); and (14) Manufacturer name and address, if available.	(6) 您知道该事件的日期（月、日、年）； (7) 报告类型（初始或后续）。如果是后续报告，您必须包括您的初次报告的报告编号； (8) 报告日期（月、日、年）； (9) 设备的大概使用年限； (10) 事件问题代码——患者代码和器械代码（参考FDA MedWatch医疗器械报告代码说明）； (11) 是否向我们发送了报告以及发送日期（月、日、年）； (12) 事件发生地点； (13) 是否向制造商发送报告以及发送日期（月、日、年）；和 (14) 制造商名称和地址（如果有）。
[79 FR 8846, Feb. 14, 2014, as amended at 80 FR 10587, Feb. 27, 2015]	[79 FR 8846，2014 年 2 月 14 日，经 80 FR 10587，2015 年 2 月 27 日修订]
Subpart E - Manufacturer Reporting Requirements	**E** 子部分 **-** 制造商报告要求
§ 803.50 If I am a manufacturer, what reporting requirements apply to me?	**§**803.50 如果我是制造商，哪些报告要求适用于我？
(a) If you are a manufacturer, you must report to us the information required by § 803.52 in accordance with the requirements of § 803.12(a), no later than 30 calendar days after the day that you receive or otherwise become aware of information, from any source, that reasonably suggests that a device that you market:	(a) 如果您是制造商，您必须根据 § 803.12(a) 的要求向我们报告 § 803.52 要求的信息，不迟于您收到或以其他方式知悉信息之日后的 30 个日历日，来自任何来源，合理地表明您销售的设备：
(1) May have caused or contributed to a death or serious injury or (2) Has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.	(1) 可能造成或促成了死亡或重伤，或 (2) 发生故障，并且如果故障再次发生，您销售的此设备或类似设备可能会导致或导致死亡或严重伤害。
(b) What information does FDA consider “reasonably known” to me?	(b) FDA 认为我“合理知道”哪些信息？
(1) You must submit all information required in this subpart E that is reasonably known to you. We consider the following information to be reasonably known to you:	(1) 您必须提交本 E 部分中要求的所有您合理知道的信息。我们认为您可以合理地了解以下信息：
(i) Any information that you can obtain by contacting a user facility, importer, or other initial reporter; (ii) Any information in your possession; or	(i) 您可以通过联系用户设施、进口商或其他初始报告者获得的任何信息； (ii) 您拥有的任何信息；或者

(iii) Any information that you can obtain by analysis, testing, or other evaluation of the device.	(iii) 您可以通过对设备进行分析、测试或其他评估获得的任何信息。
(2) You are responsible for obtaining and submitting to us information that is incomplete or missing from reports submitted by user facilities, importers, and other initial reporters.	(2) 您有责任获取并向我们提交用户设施、进口商和其他初始报告者提交的报告中不完整或缺失的信息。
(3) You are also responsible for conducting an investigation of each event and evaluating the cause of the event. If you cannot submit complete information on a report, you must provide a statement explaining why this information was incomplete and the steps you took to obtain the information. If you later obtain any required information that was not available at the time you filed your initial report, you must submit this information in a supplemental report under § 803.56 in accordance with the requirements of § 803.12(a).	(3) 您还负责对每个事件进行调查并评估事件的原因。如果您无法提交完整的报告信息，您必须提供一份声明，解释为什么该信息不完整以及您为获取该信息所采取的步骤。如果您后来获得了在您提交初始报告时不可用的任何所需信息，您必须根据 § 803.12(a) 的要求，根据 § 803.56 在补充报告中提交该信息。
§ 803.52 If I am a manufacturer, what information must I submit in my individual adverse event reports?	**§**803.52 如果我是制造商，我必须在个人不良事件报告中提交哪些信息？
You must include the following information in your reports, if known or reasonably known to you, as described in § 803.50(b). These types of information correspond generally to the format of Form FDA 3500A:	如 § 803.50(b) 所述，如果您知道或合理知道，您必须在报告中包含以下信息。这些类型的信息通常对应于表格 FDA 3500A 的格式：
(a) Patient information (Form FDA 3500A, Block A). You must submit the following:	(a) 患者信息（表格 FDA 3500A，A 块）。您必须提交以下内容：
(1) Patient name or other identifier; (2) Patient age at the time of event, or date of birth; (3) Patient gender; and (4) Patient weight.	(1) 患者姓名或其他标识； (2) 事件发生时的患者年龄或出生日期； (3) 患者性别；和 (4) 患者体重。
(b) Adverse event or product problem (Form FDA 3500A, Block B). You must submit the following:	(b) 不良事件或产品问题（表格 FDA 3500A，B 块）。您必须提交以下内容：
(1) Identification of adverse event or product problem;	(1) 不良事件或产品问题的识别；
(2) Outcomes attributed to the adverse event (e.g., death or serious injury). An outcome is considered a serious injury if it is:	(2) 归因于不良事件的结果（例如，死亡或重伤）。如果结果是以下情况，则将其视为严重伤害：
(i) A life-threatening injury or illness; (ii) A disability resulting in permanent impairment of a body function or permanent damage to a body structure; or (iii) An injury or illness that requires intervention to prevent permanent impairment of a body structure or function;	(i) 危及生命的伤害或疾病； (ii) 导致身体功能永久性损伤或身体结构永久性损伤的残疾；或者 (iii) 需要干预以防止对身体结构或功能造成永久性损害的伤害或疾病；
(3) Date of event;	(3) 事件发生日期；

(4) Date of this report;	(4) 本报告日期；
(5) Description of the event or problem, including a discussion of how the device was involved, nature of the problem, patient followup or required treatment, and any environmental conditions that may have influenced the event;	(5) 事件或问题的描述，包括对设备如何参与、问题的性质、患者随访或所需治疗以及可能影响事件的任何环境条件的讨论；
(6) Description of relevant tests, including dates and laboratory data; and	(6) 相关测试的描述，包括日期和实验室数据；和
(7) Other relevant patient history including preexisting medical conditions.	(7) 其他相关患者病史，包括既往病史。
(c) Device information (Form FDA 3500A, Block D). You must submit the following:	(c) 设备信息（表格 FDA 3500A，块 D）。您必须提交以下内容：
(1) Brand name; (2) Product Code, if known, and Common Device Name; (3) Manufacturer name, city, and state; (4) Model number, catalog number, serial number, lot number, or other identifying number; expiration date; and unique device identifier (UDI) that appears on the device label or on the device package; (5) Operator of the device (health professional, lay user/patient, other); (6) Date of device implantation (month, day, year), if applicable; (7) Date of device explantation (month, day, year), if applicable; (8) Whether the device is a single-use device that was reprocessed and reused on a patient (Yes, No)? (9) If the device is a single-use device that was reprocessed and reused on a patient (yes to paragraph (c)(8) of this section), the name and address of the reprocessor; (10) Whether the device was available for evaluation, and whether the device was returned to the manufacturer, and if so, the date it was returned to the manufacturer; and (11) Concomitant medical products and therapy dates. (Do not report products that were used to treat the event.)	(1) 品牌名称； (2) 产品代码（如果知道）和通用设备名称； (3) 制造商名称、城市和州； (4) 型号、目录号、序列号、批号或其他识别号；截止日期; 以及出现在设备标签或设备包装上的唯一设备标识符 (UDI)； (5) 设备操作者（卫生专业人员、非专业用户/患者、其他）； (6) 器械植入日期（月、日、年），如适用； (7) 器械移植日期（月、日、年），如适用； (8) 该器械是否是在患者身上再加工和重复使用的一次性器械（是，否）？ (9) 如果设备是在患者身上再处理和再利用的一次性设备（本节第 (c)(8) 段是），再处理者的名称和地址； (10) 设备是否可供评估，是否返回制造商，如果是，返回制造商的日期；和 (11) 伴随的医疗产品和治疗日期。（不要报告用于治疗事件的产品。）
(d) Initial reporter information (Form FDA 3500A, Block E). You must submit the following:	(d) 初始报告人信息（表格 FDA 3500A，E 块）。您必须提交以下内容：
(1) Name, address, and telephone number of the reporter who initially provided information to you, or to the user facility or importer;	(1) 最初向您或用户设施或进口商提供信息的报告人的姓名、地址和电话号码；

(2) Whether the initial reporter is a health professional; (3) Occupation; and (4) Whether the initial reporter also sent a copy of the report to us, if known.	(2) 初始报告人是否为卫生专业人员； (3) 职业；和 (4) 初始报告人是否也向我们发送了一份报告副本，如果知道的话。
(e) Reporting information for all manufacturers (Form FDA 3500A, Block G). You must submit the following:	(e) 所有制造商的报告信息（表格 FDA 3500A，块 G）。您必须提交以下内容：
(1) Your reporting office's contact name and address and device manufacturing site; (2) Your contact person's telephone number; (3) Your report sources; (4) Date received by you (month, day, year); (5) PMA/510k Number and whether or not the product is a combination product; (6) Type of report being submitted (e.g., 5-day, initial, followup); and (7) Your report number.	(1) 您的报告办公室的联系名称和地址以及设备制造地点； (2) 您的联系人的电话号码； (3) 您的举报来源； (4) 您收到的日期（月、日、年）； (5) PMA/510k编号及产品是否为组合产品； (6) 提交的报告类型（例如，5 天、初次、后续）；和 (7) 您的报告编号。
(f) Device manufacturer information (Form FDA 3500A, Block H). You must submit the following:	(f) 设备制造商信息（表格 FDA 3500A，块 H）。您必须提交以下内容：
(1) Type of reportable event (death, serious injury, malfunction, etc.); (2) Type of followup report, if applicable (e.g., correction, response to FDA request, etc); (3) If the device was returned to you and evaluated by you, you must include a summary of the evaluation. If you did not perform an evaluation, you must explain why you did not perform an evaluation; (4) Device manufacture date (month, day, year); (5) Whether the device was labeled for single use; (6) Evaluation codes (including event codes, method of evaluation, result, and conclusion codes) (refer to FDA MedWatch Medical Device Reporting Code Instructions); (7) Whether remedial action was taken and the type of action; (8) Whether the use of the device was initial, reuse, or unknown; (9) Whether remedial action was reported as a removal or correction under section 519(f) of the Federal Food, Drug, and Cosmetic Act, and if it was, provide the correction/removal report number; and (10) Your additional narrative; and/or	(1) 可报告事件的类型（死亡、重伤、故障等）； (2) 后续报告的类型，如果适用（例如，更正、对 FDA 要求的响应等）； (3) 如果设备被退回给您并由您进行评估，您必须附上评估摘要。如果您没有进行评估，您必须解释为什么您没有进行评估； (4) 器械生产日期（月、日、年）； (5) 器械是否标示为一次性使用； (6) 评估代码（包括事件代码、评估方法、结果和结论代码）（参见FDA MedWatch医疗器械报告代码说明）； (7) 是否采取了补救措施及措施类型； (8) 设备的使用是初次使用、重复使用还是未知； (9) 根据《联邦食品、药品和化妆品法》第 519(f) 条，补救措施是否被报告为移除或更正，如果是，请提供更正/移除报

	告编号；和 (10) 您的补充叙述；和/或
(11) Corrected data, including:	(11) 更正数据，包括：
(i) Any information missing on the user facility report or importer report, including any event codes that were not reported, or information corrected on these forms after your verification; (ii) For each event code provided by the user facility under § 803.32(e)(10) or the importer under § 803.42(e)(10), you must include a statement of whether the type of the event represented by the code is addressed in the device labeling; and (iii) If your report omits any required information, you must explain why this information was not provided and the steps taken to obtain this information.	(i) 用户设施报告或进口商报告中缺少的任何信息，包括任何未报告的事件代码，或在您验证后在这些表格上更正的信息； (ii) 对于用户设施根据 § 803.32(e)(10) 或进口商根据 § 803.42(e)(10) 提供的每个事件代码，您必须声明代码所代表的事件类型是否在设备标签中注明；和 (iii) 如果您的报告遗漏了任何必需的信息，您必须解释未提供此信息的原因以及为获取此信息而采取的步骤。
[79 FR 8846, Feb. 14, 2014, as amended at 80 FR 10587, Feb. 27, 2015]	[79 FR 8846，2014 年 2 月 14 日，经 80 FR 10587，2015 年 2 月 27 日修订]
§ 803.53 If I am a manufacturer, in which circumstances must I submit a 5-day report?	**§**803.53 如果我是制造商，在哪些情况下我必须提交 5 天报告？
You must submit a 5-day report to us with the information required by § 803.52 in accordance with the requirements of § 803.12(a) no later than 5 work days after the day that you become aware that:	您必须根据 § 803.12(a) 的要求向我们提交一份为期 5 天的报告，其中包含 § 803.52 要求的信息，并且不迟于您意识到以下情况之日起 5 个工作日：
(a) An MDR reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. You may become aware of the need for remedial action from any information, including any trend analysis or	(a) MDR 可报告事件需要采取补救措施，以防止对公众健康造成重大损害的不合理风险。您可能会从任何信息中意识到需要采取补救措施，包括任何趋势分析或
(b) We have made a written request for the submission of a 5-day report. If you receive such a written request from us, you must submit, without further requests, a 5-day report for all subsequent events of the same nature that involve substantially similar devices for the time period specified in the written request. We may extend the time period stated in the original written request if we determine it is in the interest of the public health.	(b) 我们已书面要求提交为期 5 天的报告。如果您收到我们的此类书面请求，您必须提交一份为期 5 天的报告，报告在书面请求中指定的时间段内涉及实质相似设备的所有相同性质的后续事件。如果我们确定这符合公众健康的利益，我们可能会延长原始书面请求中规定的期限。
§ 803.56 If I am a manufacturer, in what circumstances must I submit a supplemental or followup report and what are the requirements for such reports?	**§**803.56 如果我是制造商，在什么情况下我必须提交补充或跟踪报告，这些报告的要求是什么？
If you are a manufacturer, when you obtain information required under this part that you did not provide because it was not known or	如果您是制造商，当您获得本部分要求的信息时，由于在提交初始报告时不知道或

was not available when you submitted the initial report, you must submit the supplemental information to us within 30 calendar days of the day that you receive this information. You must submit the supplemental or followup report in accordance with the requirements of § 803.12(a). On a supplemental or followup report, you must:	无法获得而未提供，您必须在当天的 30 个日历日内向我们提交补充信息您收到此信息。您必须按照 § 803.12(a)的要求提交补充报告或后续报告。在补充报告或后续报告中，您必须：
(a) Indicate that the report being submitted is a supplemental or followup report;	(a) 表明所提交的报告是补充报告或后续报告；
(b) Submit the appropriate identification numbers of the report that you are updating with the supplemental information (e.g., your original manufacturer report number and the user facility or importer report number of any report on which your report was based), if applicable; and	(b) 如果适用，请提交您正在使用补充信息更新的报告的适当识别号（例如，您的原始制造商报告编号和您的报告所依据的任何报告的用户设施或进口商报告编号）；和
(c) Include only the new, changed, or corrected information.	(c) 仅包括新的、更改的或更正的信息。
§ 803.58 Foreign manufacturers.	**§**803.58 国外厂商。
(a) Every foreign manufacturer whose devices are distributed in the United States shall designate a U.S. agent to be responsible for reporting in accordance with § 807.40 of this chapter. The U.S. designated agent accepts responsibility for the duties that such designation entails. Upon the effective date of this regulation, foreign manufacturers shall inform FDA, by letter, of the name and address of the U.S. agent designated under this section and § 807.40 of this chapter, and shall update this information as necessary. Such updated information shall be submitted to FDA, within 5 days of a change in the designated agent information.	(a) 其设备在美国销售的每个外国制造商都应指定一名美国代理负责根据本章第 807.40 条进行报告。美国指定代理人承担此类指定所带来的职责。自本法规生效之日起，外国制造商应将根据本节和本章第 807.40 节指定的美国代理人的名称和地址以信函形式通知 FDA，并应根据需要更新此信息。此类更新信息应在指定代理信息更改后的 5 天内提交给 FDA。
(b) U.S.-designated agents of foreign manufacturers are required to:	(b) 外国制造商的美国指定代理商必须：
(1) Report to FDA in accordance with §§ 803.50, 803.52, 803.53, and 803.56; (2) Conduct, or obtain from the foreign manufacturer the necessary information regarding, the investigation and evaluation of the event to comport with the requirements of § 803.50; (3) Forward MDR complaints to the foreign manufacturer and maintain documentation of this requirement; (4) Maintain complaint files in accordance with § 803.18; and (5) Register, list, and submit premarket notifications in accordance with part 807 of this chapter.	(1) 根据§§ 803.50、803.52、803.53 和 803.56 向 FDA 报告； (2) 进行或从外国制造商处获取有关事件调查和评估的必要信息，以符合 §803.50 的要求； (3) 将 MDR 投诉转发给外国制造商并保存此要求的文件； (4) 按照 § 803.18 维护投诉文件；和 (5) 按照本章第 807 部分的规定登记、列出和提交上市前通知。
Effective Date Note: At 79 FR 8846, Feb. 14, 2014, part 803 was revised. At 79 FR 8855, Feb. 14, 2014, § 803.58 was stayed	生效日期注： 在 2014 年 2 月 14 日的 79 FR 8846

indefinitely.	中，对第 803 部分进行了修订。在 2014 年 2 月 14 日的 79 FR 8855 中，§803.58 被无限期保留。