Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Absorbable Poly(hydroxybutyrate) Surgical Suture Produced by Recombinant DNA Technology

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Food and Drug Administration
Center for Devices and Radiological Health

Plastic and Reconstructive Surgery Devices Branch
Division of General, Restorative, and Neurological Devices
Office of Device Evaluation

Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. Alternatively, electronic comments may be submitted to **Regulations.gov (http://www.regulations.gov)**. Please identify your comments with the docket number listed in the notice of availability that publishes in the Federal Register announcing the availability of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet. You may also send an e-mail request to **CDRH-Guidance@fda.hhs.gov (mailto:CDRH-Guidance@fda.hhs.gov)** to receive a copy of the guidance. Please use the document number (1629) to identify the guidance you are requesting.

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1. Introduction

This guidance document was developed as a special control guidance to support the classification of the absorbable poly(hydroxybutyrate) surgical suture produced by recombinant DNA technology into class II (special controls). The device is an absorbable poly(hydroxybutyrate) surgical suture made of material isolated from prokaryotic cells produced by recombinant DNA technology. The device is intended for use in general soft tissue approximation and ligation. This guidance is issued in conjunction with a Federal Register notice announcing the classification of the device.

Following the effective date of the final rule classifying the device, any firm submitting a premarket notification (510(k)) for an **Absorbable Poly(hydroxybutyrate) Surgical Suture Produced by Recombinant DNA Technology** will need to address the issues covered in this special control guidance. The firm must show that its device addresses the issues of safety and effectiveness identified in this guidance, either by meeting the recommendations of this guidance or by some other means that provides equivalent assurances of safety and effectiveness.

The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe need to be addressed before your device can be marketed. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to follow the guidance and address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that there is a less burdensome way to address the issues, you should follow the procedures outlined in the "**A Suggested Approach to Resolving Least Burdensome Issues (/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm)**" document.

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2. Background

FDA believes that special controls, when combined with the general controls, will be sufficient to provide reasonable assurance of the safety and effectiveness of an absorbable poly(hydroxybutyrate) surgical suture produced by recombinant DNA technology. Thus, a manufacturer who intends to market a device of this generic type must (1) conform to the general controls of the Federal Food, Drug, and Cosmetic Act (the Act), including the premarket notification requirements described in 21 CFR 807 Subpart E, (2) address the specific risks to health associated with an absorbable poly(hydroxybutyrate) surgical suture produced by recombinant DNA technology identified in this guidance, and (3) obtain a substantial equivalence determination from FDA prior to marketing the device.

This special control guidance document identifies the classification regulation and product code for the absorbable poly(hydroxybutyrate) surgical suture produced by recombinant DNA technology (Please refer to **Section 4. Scope**). In addition, other sections of this special control guidance document list the risks to health identified by FDA and describe measures that, if

followed by manufacturers and combined with the general controls, will generally address the risks associated with the absorbable poly(hydroxybutyrate) surgical suture produced by recombinant DNA technology and lead to a timely 510(k) review. This document supplements other FDA documents regarding the content requirements of a premarket notification submission. You should also refer to 21 CFR 807.87, **Format for Traditional and Abbreviated 510(k)s**[1], and **"How to Prepare a 510(k) Submission"**[2] on FDA Device Advice.

As described in the guidance entitled, **The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications; Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080187.htm)**, a manufacturer may submit a Traditional 510(k) or has the option of submitting either an Abbreviated 510(k) or a Special 510(k). FDA believes an Abbreviated 510(k) provides the least burdensome means of demonstrating substantial equivalence for a new device, particularly once a class II special controls guidance document has been issued. Manufacturers considering certain modifications to their own cleared devices may lessen the regulatory burden by submitting a Special 510(k).

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3. The Content and Format of an Abbreviated 510(k) Submission

An Abbreviated 510(k) submission must include the required elements identified in 21 CFR 807.87, including the proposed labeling for the device sufficient to describe the device, its intended use, and the directions for its use. In an Abbreviated 510(k), FDA may consider the contents of a summary report to be appropriate supporting data within the meaning of 21 CFR 807.87(f) or (g); therefore, we recommend that you include a summary report. The report should describe how this special control guidance document was used during the device development and testing and should briefly describe the methods or tests used and a summary of the test data or description of the acceptance criteria applied to address the risks identified in this document, as well as any additional risks specific to your device. This section suggests information to fulfill some of the requirements of section 807.87 as well as some other items that we recommend you include in an Abbreviated 510(k).

Coversheet

The coversheet should prominently identify the submission as an Abbreviated 510(k) and cite the title of this special controls guidance document.

Proposed labeling

Proposed labeling should be sufficient to describe the device, its intended use, and the directions for its use. (Please refer to **Section 11** for specific information that should be included in the labeling for devices of the type covered by this guidance document.)

Summary report

We recommend that the summary report contain:

Description of the device and its intended use

We recommend that the description include a complete discussion of the performance specifications and, when appropriate, detailed, labeled drawings of the device. (Please refer to **Section 5. Device Description** for specific information that we recommend you include in the device description for devices of the types covered by this guidance document.) You should also submit an “indications for use” enclosure[3].

Description of device design requirements

We recommend that you include a brief description of the device design requirements.

Identification of the risk analysis method

We recommend that you identify the Risk Analysis method(s) you used to assess the risk profile, in general, as well as the specific device's design and the results of this analysis. (Please refer to **Section 6. Risks to Health** for the risks to health generally associated with the use of this device that FDA has identified.)

Discussion of the device characteristics

We recommend that you discuss the device characteristics that address the risks identified in this class II special controls guidance document, as well as any additional risks identified in your risk analysis.

Description of the performance aspects

We recommend that you include a brief description of the test method(s) you have used or intend to use to address each performance aspect identified in **Sections 7-10** of this class II special controls guidance document. If you follow a suggested test method, you may cite the method rather than describing it. If you modify a suggested test method, you may cite the method but should provide sufficient information to explain the nature of and reason for the modification. For each test, you may either (1) briefly present the data resulting from the test in clear and concise form, such as a table, **or** (2) describe the acceptance criteria that you will apply to your test results[4]. (See also 21 CFR 820.30, Subpart C - Design Controls for the Quality System Regulation.)

Reliance on standards

If you choose to rely on a recognized standard for any part of the device design or testing, you may include either a:

- statement that testing will be conducted and meet specified acceptance criteria before the device is marketed; or
- declaration of conformity to the standard[5].

Because a declaration of conformity is based on results from testing, we believe you cannot properly submit a declaration of conformity until you have completed the testing the standard describes. For more information, please refer to section 514(c)(1)(B) of the Act and the FDA guidance, **Use of Standards in Substantial Equivalence Determinations; Final Guidance for Industry and FDA (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073752.htm)**.

If it is not clear how you have addressed the risks identified by FDA or additional risks identified through your risk analysis, we may request additional information about aspects of the device's performance characteristics. We may also request additional information if we need it to assess the adequacy of your acceptance criteria. (Under 21 CFR 807.87(l), we may request any additional information that is necessary to reach a determination regarding substantial equivalence.)

As an alternative to submitting an Abbreviated 510(k), you can submit a Traditional 510(k) that provides all of the information and data required under 21 CFR 807.87 and described in this guidance. A Traditional 510(k) should include all of your methods, data, acceptance criteria, and conclusions. Manufacturers considering certain modifications to their own cleared devices should consider submitting Special 510(k)s.

The general discussion above applies to any device subject to a special controls guidance document. The following is a specific discussion of how you should apply this special controls guidance document to a premarket notification submission for an absorbable Poly(hydroxybutyrate) Surgical Suture Produced by Recombinant DNA Technology.

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4. Scope

The scope of this document is limited to the device described in 21 CFR 878.4494 below, class II, product code NWJ.

Section 878.4494 Absorbable Poly(hydroxybutyrate) Surgical Suture Produced by Recombinant DNA Technology

(a) *Identification.* An absorbable poly(hydroxybutyrate) surgical suture is an absorbable surgical suture made of material isolated from prokaryotic cells produced by recombinant DNA technology. The device is intended for use in general soft tissue approximation and ligation.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled, "Class II Special Controls Guidance Document: Absorbable Poly(hydroxybutyrate) Surgical Suture Produced by Recombinant DNA Technology." For the availability of this guidance document see § 878.1(e).

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5. Device Description

We recommend that you identify your device by the regulation and product code described in **section 4. Scope**.

Your submission should describe how you manufacture the raw polymer material, the general characteristics of the cell line, and the development of the master cell bank as recommended in **Guidance for Industry – For the Submission of Chemistry, Manufacturing, and Controls Information for a Therapeutic Recombinant DNA-Derived Product or a Monoclonal Antibody Product for In Vivo Use**[6].

We recommend your device description include the:

- molecular weight and polydispersity of the polymer
- physiochemical characterization of the material, which includes all chemical, physical, and mechanical testing of the product
- biocompatibility of the material (see Section 7).

Release Specifications

Your device description should include the final product release specifications. We recommend that your release specifications include the following criteria:

Specification	Recommended Method
Polymer composition and test for purity	NMR – Nuclear Magnetic Resonance IR – InfraRed Spectroscopy
Molecular weight and polydispersity	GPC- Gel Permeation Chromotography
Volatile residuals	Loss on Drying
Presence of heavy metals	Qualitative Measurement of Heavy Metals Content, e.g., USP Class VI <231>
Presence of Impurities	• Residue on Ignition • Gas Chromatography, e.g., GC butanolysis • Elemental Analysis for Carbon, Hydrogen Content • Elemental Analysis for Nitrogen Content, e.g., Kjeldahl method
Sulfur content	Qualitative Measurement of Sulfur Content, e.g., Inductively Coupled Plasma (ICP) method
Pyrogen levels	L imulus Amebocyte Lysate (LAL) or rabbit pyrogen assay

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6. Risks to Health

In the table below, FDA has identified the risks to health generally associated with the use of the Absorbable Poly(hydroxybutyrate) Surgical Suture Produced by Recombinant DNA Technology addressed in this document. The measures recommended to mitigate these identified risks are given in this guidance document, as shown in the table below. You should also conduct a risk analysis, before submitting your 510(k), to identify any other risks specific to your device. The 510(k) should describe the risk analysis method and include the results. If you elect to use an alternative approach to address a particular risk identified in this document, or have identified risks additional to those in this document, you should provide sufficient detail to support the approach you have used to address that risk.

Identified Risk	Recommended Mitigation Measures
Improper Selection and Use	9. Physical and Performance Characteristics 7. Biocompatibility 12. Labeling
Suture Breakage	9. Physical and Performance Characteristics 10. Expiration Dating
Adverse Tissue Reaction (i.e., irritation, inflammation, immune response)	7. Biocompatibility
Infection	8. Sterility

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7. Biocompatibility

We recommend you conduct biocompatibility testing as described in the FDA guidance, **Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part-1: Evaluation and Testing** (the Biocompatibility guidance)[7]. We recommend you select biocompatibility tests appropriate for the duration and level of contact with your device. In addition, we also recommend you evaluate immunogenicity by testing for:

- sensitization
- intracutaneous irritation
- evaluating local tissue response during implantation studies.

We recommend you conduct the tests described above on final finished sterilized sutures. If identical materials and identical material processing are used in a predicate device with the same type and duration of patient contact, you may identify the predicate device in lieu of providing biocompatibility testing.

To address the concern regarding potential drift in the biological synthesis of the polymer, as well as co-purifying impurities and immunogens that might be covalently bound to the polymer, we recommend you conduct the animal testing as follows. On purified polymer from several batches, we recommend you conduct a four week subcutaneous implantation study to evaluate the local tissue response to the polymer following ISO 10993: Biological Evaluation of Medical Devices, Part 6: Tests for Local Effects after Implantation or equivalent method. We also recommend you describe the result of histopathology examinations of the implantation site and consider examining sera collected from these animals for evidence of a humoral response against the device.

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8. Sterility

We recommend that you provide sterilization information as described in the **Updated 510(k) Sterility Review Guidance K90-1**[8]. The device should be sterile with a sterility assurance level (SAL) of 1 x 10 -6 using a sterilization cycle validated in accordance with the Quality System Regulation 21 CFR Part 820. If the product or process incorporates material of animal or human origin (such as tissue culture medium with fetal calf serum), then you should describe the methods and techniques used for viral inactivation and you should describe how these methods were validated. The FDA believes that sterilization methods should reduce the amount of virus in the final product below 1 infectious unit per 106 devices. (Please refer to Section 13 for more information.)

Because of the nature of surgical sutures, we recognize the final device can be marketed in a non-sterile form. We encourage you, however, to market your device in sterile form. If you intend to market your device in non-sterile form for subsequent sterilization in a healthcare facility, we recommend you provide clear and adequate instructions for sterilization in your instructions for use. If your device is marketed in a non-sterile form, you should prominently indicate in your package labeling and instructions for use that your device is provided non-sterile for subsequent sterilization in a healthcare facility.

Sutures are implanted devices and, therefore, we recommend you test the devices for pyrogenicity. We recommend you provide a:

- description of the method used to make the determination, e.g., limulus amebocyte lysate (LAL);

- identification of the testing endpoint reached and rationale for selecting that endpoint;
- description of the extraction technique used to obtain the test fluid from the test device, showing that all clinically relevant contact surfaces of the test device were assessed and;
- identification of the reference method used, e.g., United States Pharmacopeia (USP), ANSI/AAMI ST 72:2002, Bacterial endotoxins - Test methodologies, routine monitoring, and alternatives to batch testing or FDA guidance.

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9. Physical and Performance Characteristics

We recommend you conduct the physical and performance testing described in the guidance entitled **Class II Special Controls Guidance Document: Surgical Sutures**[9] on your final finished sterilized device.

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10. Expiration Dating

Expiration dating should be supported by stability study results demonstrating that the critical parameters of a device (e.g., sterility, package integrity, coating integrity, delivery system tensile strength tests, deployment, and fatigue) will perform consistently during its entire shelf life.

The appropriateness of accelerated stability data is determined by device composition. The value of accelerated stability test data depends on identical decomposition mechanisms at both standard and elevated temperatures. When device failure or decomposition occurs by different mechanisms at the standard and elevated temperatures of accelerated stability testing (e.g., loss of sterility at 25ºC versus protein denaturation at 50ºC), we believe accelerated stability test data is not appropriate. Generally, accelerated stability data may be appropriate if you have validated it by real time aging studies or there is peer-review literature showing your material decomposes by similar mechanisms at standard and elevated temperatures.

In addition, we recommend you describe the packaging that is used to maintain sterility.

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11. Clinical Studies

In accordance with the Least Burdensome provisions of the act, the agency will rely upon well-designed bench and/or animal testing rather than requiring clinical studies for new devices unless there is a specific justification for asking for clinical information to support a determination of substantial equivalence. While, in general, clinical studies may not be needed for most absorbable poly(hydroxybutyrate) surgical sutures produced by recombinant DNA technology, FDA may recommend that you collect clinical data for an absorbable poly(hydroxybutyrate) surgical suture produced by recombinant DNA technology with any one of the following:

- indications for use dissimilar from a legally marketed absorbable poly(hydroxybutyrate) surgical suture produced by recombinant DNA technology of the same type
- designs dissimilar from designs previously cleared under a premarket notification
- new technology, i.e., technology different from that used in a legally marketed absorbable poly(hydroxybutyrate) surgical suture produced by recombinant DNA technology.

FDA will always consider alternatives to clinical testing when the proposed alternatives are supported by an adequate scientific rationale.

If a clinical study is needed to demonstrate substantial equivalence, i.e., conducted prior to obtaining 510(k) clearance of the device, the study must be conducted under the Investigational Device Exemptions (IDE) regulation, 21 CFR Part 812. Generally, FDA believes that the absorbable poly(hydroxybutyrate) surgical suture produced by recombinant DNA technology addressed by this

guidance document is a non-significant risk device. Therefore the study would be subject to the abbreviated requirements of 21 CFR 812.2(b)[10]. In addition to the requirements of section 21 CFR 812.2(b), sponsors of such trials must comply with the regulations governing institutional review boards (21 CFR Part 56) and informed consent (21 CFR Part 50).

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12. Labeling

The premarket notification must include labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). The following suggestions are aimed at assisting you in preparing labeling that satisfies the requirements of 21 CFR Part 801[11].

We recommend that you follow the labeling recommendations in the guidance **Class II Special Controls Guidance Document: Surgical Sutures**[12] ; in addition, we recommend your labeling caution users that trace amounts of antibiotics may be present in the device. Your labeling should also indicate the family or type of antibiotic that may be present.

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13. Manufacturing

Your manufacturing process must conform to the requirements of 21 CFR Part 820. To assist you in meeting these requirements, we recommend you document in your design history files the origin and safety of the genetically modified cell line as described in:

- **Guidance for Industry – For the Submission of Chemistry, Manufacturing, and Controls Information for a Therapeutic Recombinant DNA-Derived Product or a Monoclonal Antibody Product for In Vivo Use (/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/General/UCM173477.pdf)**.
- **Points to Consider in the Production and Testing of New Drugs and Biologicals Produced by Recombinant DNA Technology (/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/OtherRecommendationsforManufacturers/UCM062750.pdf)**.
- **Supplement to the Points to Consider on Production and Testing of New Drugs and Biologics Produced by rDNA Technology: Nucleic Acid Characterization and Genetic Stability (/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/OtherRecommendationsforManufacturers/UCM062777.pdf)**.
- **Points to Consider in the Characterization of Cell Lines Used to Produce Biologicals (/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/OtherRecommendationsforManufacturers/UCM062745.pdf)**.

In addition to the above, we recommend that your Receiving, In Process, and Finished Device Acceptance Criteria (21 CFR 820.80) include an assessment of the biocompatibility of the purified polymer. We recommend that you conduct a four week subcutaneous implantation study on purified polymer from production runs to evaluate the local tissue response as described in ISO 10993: Biological Evaluation of Medical Devices, Part 6: Tests for Local Effects after Implantation or an equivalent method. The results should be documented in your Device History Record (see 21 CFR 820.3(i), 820.184). Because of the complexity of the manufacturing of these devices, FDA may request an inspection of the manufacturing facility to assess compliance with the Quality System Regulation.

If the product or process incorporates material of animal or human origin (such as tissue culture medium with fetal calf serum), then the processing methods and sterilization techniques should be validated with regard to the inactivation and removal of viruses. Specifically, sterilization methods should reduce the amount of virus in the final product below 1 infectious unit per 106 devices. Such data can be obtained by determining the amount of virus in the unprocessed source material and the viral inactivation properties of scaled down versions of specific production and sterilization methods (e.g., acid extraction of collagen or dry heat sterilization) using appropriate model viruses. We recommend you follow **Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin**, (ICH Harmonized Tripartite Draft Guideline)[13] for your study design and selection of model

viruses. The final results of these studies should demonstrate that the sum of the log clearance of virus from the selected processing steps and sterilization processes are at least six logs greater than the concentration of virus anticipated in the unprocessed source material. These results should be documented in your Device Master Record (see 21 CFR 820.3(j), 820.181).

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[1] **Format for Traditional and Abbreviated 510(k)s (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm)**

[2] **Premarket Notification 510(k) (/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm)**

[3] Refer to **Indications for Use Form (http://www.fda.gov/downloads/aboutfda/reportsmanualsforms/forms/ucm360431.pdf)** (PDF File Size: 1.03MB) for the recommended format.

[4] If FDA makes a substantial equivalence determination based on acceptance criteria, the subject device should be tested and shown to meet these acceptance criteria before being introduced into interstate commerce. If the finished device does not meet the acceptance criteria and, thus, differs from the device described in the cleared 510(k), FDA recommends that submitters apply the same criteria used to assess modifications to legally marketed devices (21 CFR 807.81(a)(3)) to determine whether marketing of the finished device requires clearance of a new 510(k).

[5] See **Required Elements for a Declaration of Conformity to a Recognized Standard (Screening Checklist for All Premarket Notification [510(K)] Submissions) (/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142706.htm)**.

[6] Guidance for Industry – **For the Submission of Chemistry, Manufacturing, and Controls Information for a Therapeutic Recombinant DNA-Derived Product or a Monoclonal Antibody Product for In Vivo Use (/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/General/UCM173477.pdf)**.

[7] **Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices May 1, 1995 (G95-1) (ssLINK/ucm080735.htm)**

[8] **Updated 510(k) Sterility Review Guidance K90-1 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072783.htm)**

[9] **Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072698.htm)**.

[10] **See Significant Risk and Nonsignificant Risk Medical Device Studies (/downloads/RegulatoryInformation/Guidances/UCM126418.pdf)**

[11] Although final labeling is not required for 510(k) clearance, final labeling must comply with the requirements of 21 CFR Part 801 before a medical device is introduced into interstate commerce. In addition, final labeling for prescription medical devices must comply with 21 CFR 801.109. Labeling recommendations in this guidance are consistent with the requirements of Part 801.

[12] **Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072698.htm)**.

[13] **Q5A Viral Safety Evaluation of Biotechnology Products Derived From Cell Lines of Human or Animal Origin (/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073454.pdf)**

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More in Guidance Documents (Medical Devices and Radiation-Emitting Products)

(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm)

Cross-Center Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081752.htm)

Office of Compliance Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070269.htm)

Office of the Center Director Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110228.htm)

Office of Communication and Education Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070271.htm)

Office of Device Evaluation Final Guidance 2010 - 2016 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm198577.htm)

Office of Device Evaluation Final Guidance 1998 - 2009 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070272.htm)

Office of Device Evaluation Final Guidance 1976 - 1997 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080283.htm)

Office of In Vitro Diagnostics and Radiological Health Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070274.htm)

Office of Surveillance and Biometrics Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070275.htm)

Office of Science and Engineering Laboratories Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070277.htm)

Draft Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm407274.htm)

Radiation-Emitting Products Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm283507.htm)

Withdrawn Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm425025.htm)