Class II Special Controls Guidance Document: Implantable Intra-Aneurysm Pressure Measurement System - Guidance for Industry and FDA Staff

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

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Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, 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 (1589) to identify the guidance you are requesting.

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Guidance for Industry and FDA Staff
Class II Special Controls Guidance Document: Implantable Intra-Aneurysm Pressure Measurement System

1. Introduction

This guidance document was developed as a special control guidance to support the classification of the implantable intra-aneurysm pressure measurement system into class II (special controls). The device is intended for measuring intrasac pressure during and upon completion of endovascular procedures. It may be used as an adjunctive tool in the detection of intraoperative leaks following stent-graft placement (i.e., endoleaks). This guidance is issued in conjunction with a Federal Register notice announcing the classification of the intra-aneurysm pressure measurement system.

Following the effective date of the final rule classifying the device, any firm submitting a premarket notification (510(k)) for an intra-aneurysm pressure measurement system will need to address the issues covered in the 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 the intra-aneurysm pressure measurement system. Thus, a manufacturer who intends to market a device of this generic type should (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 intra-aneurysm pressure measurement system 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 intra-aneurysm pressure measurement system (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 intra-aneurysm pressure measurement system 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 and "**How to Prepare a 510(k) Submission**" on FDA Device Advice.[1]

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 reduce 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 H** 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. You should also submit an "indications for use" enclosure.[2]

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 5. 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 A-G, I-L** 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.[3] (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.[4]

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 implantable intra-aneurysm pressure measurement system.

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4. Scope

The scope of this document is limited to the devices described below.

Implantable intra-aneurysm pressure measurement system (sensor), 21 CFR § 870.2855, Class II (special controls), product code, NQH.

An implantable intra-aneurysm pressure measurement system is a device used to measure the intra-sac pressure in a vascular aneurysm. The device consists of a pressure transducer that is implanted into the aneurysm and a monitor that reads the pressure from the transducer.

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5. Risks to Health

In the table below, FDA has identified the risks to health generally associated with the use of the device 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 and submit the results. The 510(k) should describe the risk analysis method. 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 (See the corresponding subheading in section 6)**
	A. Biocompatibility
Adverse tissue reaction	F. Sterility
	H. Labeling
Migration of implanted sensor	B. Bench Testing K. Animal Testing L. Clinical Testing
Inaccurate sensor information	B. Bench Testing K. Animal Testing
Failure of implanted sensor	B. Bench Testing H. Labeling K. Animal Testing L. Clinical Testing
Failure of delivery system	B. Bench Testing K. Animal Testing

Failure of electronic monitor	B. Bench Testing K. Animal Testing
	C. Software Validation
	H. Labeling
Electromagnetic interference	D. Electromagnetic Compatibility H. Labeling
Electrical hazards	E. Electrical Safety Testing H. Labeling
Magnetic resonance imaging incompatibility	G. Magnetic Resonance Imaging Compatibility H. Labeling
Ultrasound incompatibility	I. Ultrasound Compatibility H. Labeling
External defibrillation incompatibility	J. Defibrillator Compatibility H. Labeling
Failure to detect and/or diagnose an endoleak that requires intervention	L. Clinical Testing

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6. Recommended Mitigation Measures

We believe that the following special controls, when combined with the general controls of the Act, will provide reasonable assurance of the safety and effectiveness of this type of device in a premarket notification submission.

A. Biocompatibility

We recommend that you submit the results of biocompatibility testing as described in the FDA-modified **Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part-1: Evaluation and Testing**[5] for permanent duration (greater than 30 days) implanted devices that contact blood. Testing should include, but is not limited to, cytotoxicity, sensitization, irritation, acute systemic toxicity, genotoxicity, implantation, chronic toxicity, and carcinogenicity.

If *identical* materials are used in a predicate device with the same indication, same type of tissue, and same contact duration, you may identify the predicate device in lieu of biocompatibility testing. Materials are identical if they have the identical chemical formulation and identical manufacturing processes.

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B. Bench Testing

We recommend that pre-clinical testing be performed to demonstrate that the sensor will accurately measure pressure over a normal physiologic range after implantation within the body. This testing should be performed to assess the probability of sensor or monitor failure and the means by which such failure can be mitigated or is apparent to the user. The delivery system should also be tested to ensure proper performance to design specifications and to assess failure modes and probabilities. Bench testing may also be used to assess the likelihood of migration of the implanted sensor that may affect performance.

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C. Software Validation<

We recommend that you submit sufficient evidence of performance for software-controlled medical devices. The degree of evidence is determined by the "level of concern" described in the FDA guidance document titled, **Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.**[6] The "level of concern" is related to the risks associated with software failure and may be minor, moderate, or major. The level of concern for this device is likely to be moderate.

We recommend that software documentation describe the role of the software included in the device and include performance testing to demonstrate that the software functions as designed.

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D. Electromagnetic Compatibility

We recommend that you demonstrate the electromagnetic compatibility (EMC) of the device (i.e., sensor and monitor together) by following the EMC testing methods in IEC 60601-1-2 (Second Edition, 2001) Medical electrical equipment – Part 1: General requirements for safety; Electromagnetic compatibility - Requirements and Tests, or a method that provides equivalent assurances of electromagnetic compatibility.

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E. Electrical Safety Testing

We recommend that you demonstrate the electrical safety of the device by following the testing in IEC 60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety, or a method that provides equivalent assurances of electrical safety.

F. Sterility

The sensor and delivery system should be sterile with a sterility assurance level of 10^{-6}. As a blood contacting device, it should also be non-pyrogenic. We recommend that you provide the sterilization information described in the guidance, **Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA.**[7]

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G. Magnetic Resonance Imaging Compatibility

We recommend that you demonstrate the magnetic resonance imaging safety and compatibility of the device by following the test methods described in these standards or an equivalent:

- ASTM F2052-02 Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
- ASTM F2182-02a Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging
- ASTM F2213-04 Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment
- ASTM F2119-01 Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants.

In addition, we recommend that you address the EMC concerns for implant exposure to the significant magnetic emissions from magnetic resonance imaging (MRI), including concerns for implant malfunction or damage from MRI exposure.

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H. Labeling

The premarket notification should 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.[8]

Directions for use

As a prescription device, under 21 CFR 801.109, the device is exempt from having adequate directions for lay use. Nevertheless, we recommend providing clear and concise instructions that delineate the technological features of the specific device and how the device is to be used on patients. Instructions should encourage local/institutional training programs designed to familiarize users with the features of the device and how to use it in a safe and effective manner. If there are any precautions or warnings that relate to packaging or sterility, these should be repeated on the package labels.

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I. Ultrasound Compatibility

We recommend that you demonstrate the ultrasound compatibility of your device by following the recommendations in ISO 14708-1, part 22, or an equivalent.

J. Defibrillator Compatibility

We recommend that you demonstrate the compatibility of your device with external defibrillators by following the recommendations in ISO 14708-1, part 20.2, or its equivalent.

K. Animal Testing

We recommend that you evaluate the functionality and the safety of the implantable intra-aneurysm pressure measurement system through animal studies. We recommend you perform *in vivo* testing of the sensor that demonstrates under conditions of use, the sensor accurately measures pressure across the physiologic range. We also recommend you provide evidence that the mechanical and structural integrity of the sensor will be maintained when subjected to clinical use conditions. Additionally, animal testing should assess the probability of inappropriate device migration and evaluate the performance of the delivery system.

L. Clinical Testing

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 implantable intra-aneurysm pressure measurement systems, FDA may recommend that you collect clinical data for an implantable intra-aneurysm pressure measurement system with any one of the following:

- indications for use dissimilar from a legally marketed implantable intra-aneurysm pressure

measurement system of the same type

- designs dissimilar from designs previously cleared under a premarket notification
- new technology, i.e., technology different from that used in legally marketed implantable intra-aneurysm pressure measurement system.

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

If a clinical study is needed, we recommend that you evaluate the efficacy of the implantable intra-aneurysm pressure measurement system by demonstrating its ability to measure aneurysm sac pressure in human beings undergoing endovascular repair of aneurysms. We recommend that you also use this study to verify the device's ability to determine the presence of an endoleak (lack of seal), guide the physician in determining the type of endoleak, and provide adjunctive evidence as to the success of endovascular intervention in resolving the endoleak.

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. We believe that the implantable intra-aneurysm pressure measurement system addressed by this guidance document is a significant risk device as defined in 21 CFR 812.3(m).[9] In addition to the requirement of having an FDA-approved IDE, 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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1. **Premarket Notification 510(k) (/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm)**

2. 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.

3. 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).

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

5. **Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices (ssLINK/ucm080735.htm)**.

6. **Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm)**.

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

8. 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.

9. See http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/UCM118082.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)