Class II Special Controls Guidance Document: Endolymphatic Shunt Tube with Valve; Guidance for Industry and FDA

Document issued on: April 29, 2002

This document supersedes Class II Special Controls Guidance Document: Endolymphatic Shunt Tube with Valve; Draft Guidance for Industry and FDA, August 15, 2001

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

Ear, Nose and Throat Devices Branch
Division of Ophthalmic and Ear, Nose and Throat Devices
Office of Device Evaluation

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to Docket Number **Docket No. 01D-0311** and the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

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1. Background

This guidance document was developed as a special control guidance to support the reclassification of the endolymphatic shunt tube with valve into class II. The device, as classified, is intended to be implanted in the inner ear to relieve the symptoms of vertigo and hearing loss due to endolymphatic hydrops of Meniere's disease. This guidance will be issued in conjunction with a Federal Register notice announcing the reclassification of this device type.

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 endolymphatic shunt tube with valve. Thus, a manufacturer who intends to market a device of this generic type should (1) conform with the general controls of the Federal Food, Drug & Cosmetic Act (the Act), including the 510(k) requirements described in **21 CFR 807 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/showCFR.cfm?CFRPart=807)** Subpart E, (2) address the specific risk[s] to health associated with endolymphatic shunt tube with valve and identified in this guidance, and, unless exempt from the premarket notification requirements of the Act, (3) receive a substantial equivalence determination from FDA prior to marketing the device.

This special control guidance document identifies the classification, product code, and classification identification for the endolymphatic shunt tube with valve. In addition, it lists the risks to health identified by FDA and serves as the special control that, when followed and combined with the general controls, will generally address the risks associated with this generic device type and lead to a timely 510(k) review and clearance. For the specific content requirements of a 510(k) submission, you should refer to **21 CFR 807.87 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/showCFR.cfm?FR=807.87)** and other agency documents on this topic, such as "**Premarket Notification 510(k) (/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm)**".

Device manufacturers may submit an Abbreviated 510(k) when: (1) a guidance documents exists, (2) a special control has been established, or (3) FDA has recognized a relevant consensus standard. FDA believes an Abbreviated 510(k) is the least burdensome means of demonstrating substantial equivalence once a Class II Special Controls Guidance Document has been issued. See also **The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications; Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080187.htm)**.

An Abbreviated 510(k) submission should include the required elements identified in **21 CFR 807.87 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/showCFR.cfm?FR=807.87)**, including a description of the device, the intended use of the device, and the proposed labeling for the device. An Abbreviated 510(k) should also include a summary report. 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 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/showCFR.cfm?FR=807.87)**(f) or (g).

The summary report should briefly describe the methods or tests used and the acceptance criteria applied to address the risks identified in this guidance document as well as any additional risks specific to your device. When a suggested test method is followed, a simple reference to the method will be an acceptable description. If there are any deviations from a suggested test method, you should provide more detailed information in the summary report to characterize the particular deviation. The summary report should also either (1) briefly present the data resulting from each test in tabular form **or** (2) describe the acceptance criteria to be applied to the test results. (See also **21 CFR 820.30 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/showCFR.cfm?FR=820.30)** Subpart C Design Controls for the Quality System Regulation.)

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 comply with 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.

2. Scope

The scope of this document is limited to the following devices:

21 CFR 874.3850 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/showCFR.cfm?FR=874.3850)
Endolymphatic Shunt Tube with Valve.

Product code: KLZ

The classification identification below identifies the device as it existed at the time of reclassification.

> An endolymphatic shunt tube with valve is a device that consists of a pressure-limiting valve associated with a tube intended to be implanted in the inner ear to relieve the symptoms of vertigo and hearing loss due to endolymphatic hydrops (increase in endolymphatic fluid) of Meniere's disease.

3. Risks to Health

FDA has identified the risks to health generally associated with the use of endolymphatic shunt tube with valve in the table below. You should also conduct a risk analysis, prior to submitting your 510(k), to identify any other risks specific to your device. The premarket notification should describe the risk analysis method. The measures recommended to mitigate the identified risks are given in this guidance document, as shown in the table below. (If a manufacturer elects to use an alternative approach to address a particular risk, or has identified risks additional to those in the guidance, you should provide sufficient detail to support the alternative approach.)

Identified risk	**Recommended mitigation measures**
adverse tissue reaction or infection	section **7**
a build-up of fluid pressure in the inner ear due to a clogged or inoperative device	section **8**, **9**
revision surgery to correct a defective device	section **6**, **8**

4. Controls

FDA believes that the measures in the following sections of this guidance, when combined with general controls, will address the identified risks to health associated with the use of the endolymphatic shunt tube with valve. 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. If you have identified any additional risks, specific to your device, your 510(k) should identify those risks, as well as the methods or tests used and the acceptance criteria applied to address them.

5. Abbreviated 510(k) Content

An Abbreviated 510(k) that relies on a Class II Special Controls Guidance Document should contain the following.

Coversheet

The coversheet should prominently identify the submission as an Abbreviated 510(k) and cite the title of the specific Class II Special Controls Guidance Document.

Items Required Under 21 CFR 807.87 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/showCFR.cfm?FR=807.87)

The items required under **21 CFR 807.87 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/showCFR.cfm?FR=807.87)** are:

- **Description of the device.** The description should include a compete discussion of the performance specifications and, when appropriate, detailed, labeled drawings of the device
- **Intended use.** You should also submit an "indications for use" enclosure. See **Indications for Use Form (http://www.fda.gov/downloads/aboutfda/reportsmanualsforms/forms/ucm360431.pdf)** (PDF File Size: 1.03MB) for the recommended format.
- **Proposed labeling.**
- **Summary report.** A summary report should describe how the Class II Special Controls Guidance Document was used to address the risks associated with the particular device type. The summary report should contain:
  - Risk analysis.
  - Description of device performance requirements.
  - Discussion of the features and functions provided to address the risks identified in this Class II Special Controls Guidance Document, as well as any additional risks identified in your risk analysis.
  - For each performance aspect identified in sections 6-9 of this Class II Special Controls Guidance document, you should briefly discuss each test method and identify your acceptance criteria. When a suggested test method is followed, a simple reference to the method will be an acceptable description. If there are any deviations from a suggested test method, you should provide more detailed information in the summary report to characterize

the particular deviation. The summary report should also either (1) briefly present the summary results from each test in tabular form **or** (2) describe the acceptance criteria to be applied to the test results. **If any test article does not meet the identified acceptance criteria, you may not market your device. Instead, you must submit a new 510(k) with revised acceptance criteria, 21 CFR 807.81 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/showCFR.cfm?FR=807.81) (a)(3). The new 510(k) must be cleared by FDA before you market your device, 21 USC 513(i)(1)(A).**

- If any part of the device design or testing relies on a recognized standard, the summary report should include: (1) a statement that testing will be conducted and meet specified acceptance criteria before the product is marketed, or (2) a declaration of conformity to the standard. **Testing must be completed before submitting a declaration of conformity to a recognized standard**. (21 USC 514(c)(2)(B)). For more information, see 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 by 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.

As an alternative to submitting an Abbreviated 510(k), you can submit a traditional 510(k) that provides all of the information and data described in this guidance. A traditional 510(k) should include all of your methods, data, acceptance criteria, and conclusions.

6. Materials Specification

Silicone rubber elastomer and silicone rubber adhesive have been used to construct the valve bodies of devices of this generic type. Likewise, the capillary tubing in devices of this type has been made of polyether block amide (PEBA). These materials have been shown to be suitable for use in endolymphatic shunt tubes with valves, i.e., these materials can be biocompatible and have chemical stability sufficient to withstand the intended physiological environment.

Valved shunts of this type should have dimensional, flexibility, strength, and durability characteristics that meet user needs. Materials used in the construction of these devices should also have tensile strength, elongation, and hardness characteristics that meet design requirements.

FDA believes that conformance with the design control requirements of the Quality System Regulation (**21 CFR 820.30 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/showCFR.cfm?FR=820.30)**) will ensure that materials used in the fabrication of devices of this type are suitable for the intended use. You should include a brief summary of the design control activities related to material selection in the summary report in any 510(k) submission.

7. Biocompatibility and Sterility

You should evaluate the biocompatibility and sterility of the materials in your device. Please refer to the guidance documents entitled **Blue Book Memo, G95-1, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" (ssLINK/ucm080735.htm)** and **Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072783.htm)**.

You should select biocompatibility tests appropriate for blood contacting devices intended for long-term implantation. If *identical* materials are used in a predicate device with the same type and duration of patient contact, you may identify the predicate device in lieu of performing biocompatibility testing.

Your summary report should contain the following information for devices sold as sterile:

- the sterilization method used in the sterilization cycle (e.g., dry heat, ethylene oxide (EtO), steam, radiation);
- a description of the method that will be used to validate the sterilization cycle (but not the validation data);
- a description of the packaging that maintains the device's sterility (but not the package integrity testing data);
- the sterility assurance level specification (SAL)[1];
- a description of the method used to make the determination, e.g., the limulus amebocyte lysate (LAL) method, if the product is labeled pyrogen free;
- the maximum levels of EtO and ethylene chlorhydrin residues, if sterilized by EtO; and
- the radiation dose, if sterilized by radiation.

8. Valve Performance

Devices of this type have exhibited a valve opening pressure of 4.3 to 6.0 inches of water (8.0 to 11 mm Hg). Endolymphatic shunt tube with valve devices should operate in this valve opening pressure range. If the valve opening pressure range of a new device differs substantially,

manufacturers should conduct studies and submit information/data to establish the acceptability of the valve opening pressure range for their device.

FDA recommends that you conduct clinical studies for endolymphatic shunt tube with valve devices when your device:

- uses designs dissimilar from designs previously cleared under a 510(k)
- uses new technology, i.e., technology different from that used in legally marketed endolymphatic shunt tube with valve devices
- makes changes in the indication for use.

Manufacturers should test each unit, i.e., 100 percent sample testing, to ensure that each unit meets the specified valve opening pressure.

9. Labeling

The premarket notification should include labeling in sufficient detail to satisfy the requirements of **21 CFR 807.87 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/showCFR.cfm?FR=807.87)**(e). Although final labeling is not required for 510(k) clearance, final labeling must comply with the requirements of **21 CFR 801 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/showCFR.cfm?CFRPart=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 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/showCFR.cfm?FR=801.109)**. The following suggestions are aimed at assisting you in complying with **21 CFR 801 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/showCFR.cfm?CFRPart=801)** and **21 CFR 801.109 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/showCFR.cfm?FR=801.109)**.

Prescription Use

Endolymphatic shunt tube with valve devices are prescription medical devices, and according to **21 CFR 801.109 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/showCFR.cfm?FR=801.109)** must bear the following statement: "Caution: Federal law restricts this device to sale by or on the order of a physician."

Intended Use/Indications for Use

The intended use/indications for use of your device should describe the device and state the medical conditions for which it is appropriate, for example:

> "An endolymphatic shunt tube with valve is a device that consists of a pressure-limiting valve associated with a tube intended to be implanted in the inner ear to relieve the symptoms of vertigo and hearing loss due to endolymphatic hydrops (increase in endolymphatic fluid) of

Meniere's disease."

Precautions

Your labeling should include a precaution recommending physicians consider more conservative methods of treatment, including medical treatment and less complex surgical procedures, such as sac surgery without shunt, before prescribing this device.

10. Investigational Device Exemptions

Because FDA considers these to be significant risk devices, any clinical study to support the clearance of a 510(k) application must be conducted under the investigational device exemptions (IDE) regulation (**21 CFR 812 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/showCFR.cfm?CFRPart=812)**).

Clinical design validation studies that are conducted after FDA clears the 510(k) are exempt from IDE requirements in accordance with **21 CFR 812.2 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/showCFR.cfm?FR=812.2)**(c)(2). However, such studies must be performed in conformance with 21 CFR parts **50 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/showCFR.cfm?CFRPart=50)** and **56 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/showCFR.cfm?CFRPart=56)**.

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[1] FDA recommends 10^{-6} for all sterile devices, except sterile devices that only contact intact skin. These should be 10^{-3}.

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)