

Guidance for Industry and FDA Staff

Class II Special Controls Guidance Document: Low Energy Ultrasound Wound Cleaner

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**U.S. Department of Health and Human Services
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 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. Alternatively, electronic comments may be submitted to <http://www.fda.gov/dockets/ecomments>. 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.

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This guidance document represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance document. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance document.

1. Introduction

This guidance document was developed as a special control guidance document to support the classification of the low energy ultrasound wound cleaner into class II (special controls). The device is intended for the cleaning and maintenance debridement of wounds. This guidance document is issued in conjunction with a Federal Register notice announcing the classification of the low energy ultrasound wound cleaner.

Following the effective date of the final rule classifying the device, any firm submitting a 510(k) for a low energy ultrasound wound cleaner will need to address the issues covered in the special control guidance document. However, the firm need only show that its device meets the recommendations of the guidance document or in some other way 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 document, 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 guidance, **A Suggested Approach to Resolving Least Burdensome Issues**, <http://www.fda.gov/cdrh/modact/leastburdensome.html>.

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FDA's guidance documents, including this guidance document, do not establish legally enforceable responsibilities. Instead, guidance documents describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance documents means that something is suggested or recommended, but not required.

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 low energy ultrasound wound cleaner. 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 & 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 the low energy ultrasound wound cleaner identified in this guidance, and (3) obtain a substantial equivalence determination from FDA prior to marketing the device. (See also 21 CFR 807.85).

This special control guidance document identifies the classification regulation and product code for the low energy ultrasound wound cleaner (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 these low energy ultrasound wound cleaners and lead to a timely 510(k) review. This document supplements other FDA documents regarding the specific 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 at <http://www.fda.gov/cdrh/devadvice/314.html>.

As described in the guidance entitled, **The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications; Final Guidance**, <http://www.fda.gov/cdrh/ode/parad510.html>, 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 FDA issues a class II special controls guidance document. Manufacturers considering certain modifications to their own cleared devices may lessen the regulatory burden by submitting a Special 510(k).

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. Labeling** for specific information that should be included in the labeling for devices of the types 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 you describe the performance specifications and, when appropriate, include detailed, labeled drawings of the device. You should also submit an “indications for use” enclosure.¹

Description of device design requirements

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

Identification of the risk analysis method

¹ Refer to <http://www.fda.gov/cdrh/ode/indicate.html> for the recommended format.

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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 6-10** of this class I 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.² (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.³

² 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).

³ See Required Elements for a Declaration of Conformity to a Recognized Standard (Screening Checklist for All Premarket Notification [510(K)] Submissions), <http://www.fda.gov/cdrh/ode/reqrecstand.html>.

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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**; <http://www.fda.gov/cdrh/ode/guidance/1131.html>.

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 510(k) for a low energy ultrasound wound cleaner device.

4. Scope

The scope of this guidance document is limited to the device described under 21 CFR 878.4410, class II, product code NRB.

Section 878.4410 Low Energy Ultrasound Wound Cleaner.

A low energy ultrasound wound cleaner uses ultrasound energy to vaporize a fluid and generate a mist that is used for the cleaning and maintenance debridement of wounds. Low levels of ultrasound energy may be carried to the wound by the saline mist.

5. Risks to Health

In the table below, FDA has identified the risks to health that may be associated with the use of the low energy ultrasound wound cleaner and the measures recommended to mitigate these risks. You should also conduct a risk analysis, prior to submitting your premarket notification, to identify any other risks specific to your device and submit the results of this analysis. 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 guidance document, or have identified risks additional

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to those in the guidance, you should provide sufficient detail to support the approach you have used to address that risk.

Identified Risk	Recommended Mitigation Measures
Delayed wound healing	Section 7. Animal or Clinical Testing
Inflammation/foreign body response	Section 9. Biocompatibility
Thermal damage	Section 6. Performance Characteristics Section 11. Labeling
Infection	Section 10. Sterility
Electrical shock	Section 8. Electrical Safety Testing

In general, for devices of this kind, we recommend that you assess electromagnetic compatibility (EMC). EMC encompasses both emissions (interference with other electronic devices) and immunity (resistance to interference with the performance of the device, created by emissions from other electronic devices).

EMC testing should demonstrate that the device will not adversely interfere with the performance of other electronic devices, such as active implantable devices, e.g., pacemakers and defibrillators. Testing should include radio frequency (RF) electromagnetic, low frequency magnetic, and conducted emissions.

EMC testing should also demonstrate that the device will perform as expected in the presence of other electrical and electronic devices or other sources of electromagnetic disturbance (EMD) in the intended environment of use (immunity). The device should operate in an acceptable manner (few EMC standards require operation within specification) during and after exposure to various forms of electromagnetic disturbance.

We also recommend that you document the results in your design history file as a part of the Quality Systems Requirements (21 CFR 820.30).

6. Performance Characteristics

We recommend that you provide the following acoustic characteristics of your device:

- the level of airborne ultrasound energy generated by the device, its spatial characteristics, and the potential of exposure of the patient or the operator to unwanted acoustic energy
- the level of ultrasound energy transmitted to the patient and the effects of the distance of the applicator from the wound
- the variability in the field from device to device and the maximum level expected from manufacturing, given the sample variability.

7. Animal or Clinical Testing

We also recommend that you demonstrate the wound cleaning performance by use of the device in animal wounds. Using the procedures recommended in the device labeling, the device should remove most of the charcoal from wounds sprayed with graphite.

We also recommend that you demonstrate bacterial removal in animal wounds sprayed with typical wound organisms such as *Pseudomonas aeruginosa*. Daily treatments should result in the reduction of bacteria by at least 3 logs after 7 daily treatments. We recommend that you use pulsatile lavage and no washing as controls.

We recommend that you demonstrate that the mist and the ultrasound energy do not destroy cells required for optimal healing. We believe that this could be accomplished by using a clinical or an animal wound healing model. For example, swine wound models allow you to make shallow wounds with microtomes and measure the time required for complete re-epithelialization compared with control wounds washed and debrided surgically. We recommend that you document the re-epithelialization histologically.

FDA will rely upon well-designed bench and/or animal testing rather than requiring clinical studies for a low energy ultrasound wound cleaner, unless there is a specific rationale for asking for clinical information to support a determination of substantial equivalence. For most low energy ultrasound wound cleaners, a clinical study may not be necessary to support a substantial equivalence determination. However, we may recommend that you collect clinical data for a low energy ultrasound wound cleaner with any one of the following:

- mechanical testing results that do not compare favorably to the testing of the predicate device
- indications for use dissimilar from low energy ultrasound wound cleaners of the same type
- design dissimilar from any design previously cleared under a premarket notification
- new technology, i.e., technology different from that used in legally marketed low energy ultrasound wound cleaner.

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

8. Electrical Safety Testing

We recommend that you evaluate the electric safety of your device, as well as its ability to function after exposure to environmental handling hazards. We recommend that you evaluate your device according to **one or more** of the following standards:

- International Electrochemical Commission (IEC) 60601-1 Medical Electrical Equipment – Part 1: General Requirements for Safety
- Underwriters Laboratory (UL) 2601-1 Amendment 1 Medical Electrical Equipment: General requirements for safety.
- American National Standards Institute (ANSI)/AAMI ES-1 Safe Current Limits for Electromedical Apparatus.

The features and design of your device and accessories will determine which of the above standards you should use and whether other standards may be appropriate in addition to, or in place of, these. The Plastic and Reconstructive Surgery Device Branch is available to discuss which standards are appropriate for a particular device design.

9. Biocompatibility

There is no significant contact between the patient and the device. However, the applicator may contact the wound for short periods, and the mist may carry leachable components from the applicator to the wound. Therefore, we recommend that you evaluate the biocompatibility of the applicator as described in the International Standard Organization (ISO) standard ISI-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing. 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 performing biocompatibility testing.

10. Sterility

FDA recommends that you address sterilization information described in the **Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA**, <http://www.fda.gov/cdrh/ode/guidance/361.html>. The device should be sterile with a sterility assurance level (SAL) of 1×10^{-6} . (For EO-sterilized devices, please also see **Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part-1: Evaluation and Testing**, <http://www.fda.gov/cdrh/g951.html>.)

11. Labeling

Your 510(k) submission 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 801.⁴

Directions for use

As a prescription device, under 21 CFR 801.109, the device is exempt from having adequate directions for lay use. Nevertheless, under 21 CFR 807.87(e), we recommend submitting clear and concise instructions that delineate the technological features of the specific device and how the device is to be used on patients. For example, we recommend that your labeling describe the distance between the applicator and the wound and, where applicable, the power setting appropriate for patient safety that provides effective cleaning.

⁴ 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 document are consistent with the requirements of part 801.