Class II Special Controls Guidance Document: Transcutaneous Air Conduction Hearing Aid System (TACHAS); Guidance for Industry and FDA

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

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

Preface

Public Comment

For 90 days following the date of publication in the Federal Register of the notice announcing the availability of this guidance, you should submit comments and suggestions regarding this document to the Docket No. 02D-0439 assigned to that notice, 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. We will consider comments when determining whether to amend this guidance.

After 90 days following the date of publication in the Federal Register of the notice announcing the availability of this guidance, you may submit comments and suggestions at any time for Agency consideration to Dockets Management Branch. Comments may not be acted upon by the Agency until the document is next revised or updated.

For questions regarding the use or interpretation of this guidance contact Eric A. Mann, M.D., Ph.D., Ear, Nose and Throat Devices Branch at (301) 594-2080 or by email exm@cdrh.fda.gov.

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This document is intended to provide guidance. It represents the Agency'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 the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

1. Introduction

This guidance document was developed as a special controls guidance to support the classification of the Transcutaneous Air Conduction Hearing Aid System (TACHAS) into Class II (Special Controls). The device is intended to compensate for impaired hearing without occluding the ear canal. It consists of an air conduction hearing aid attached to a surgically fitted tube system, which is placed through the soft tissues between the post auricular region and the outer ear canal.

This guidance is issued in conjunction with a Federal Register notice announcing the classification of the TACHAS.

Following the effective date of this final classification rule, any firm submitting a 510(k) premarket notification for a TACHAS will need to address the issues covered in the special controls guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

2. Background

FDA believes that special controls, when combined with the general controls[1], will be sufficient to provide reasonable assurance of the safety and effectiveness of the TACHAS. 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 TACHAS identified in this guidance and, (3) obtain a substantial equivalence determination from FDA prior to marketing the device, unless exempt from the premarket notification requirements of the Act (refer to 21 CFR 807.85).

[1] Because this device meets the definition of a hearing aid, the general controls for this device include the Special Requirements for Specific Devices described in 21 CFR 801.420 and 801.421.

This special controls guidance document identifies the classification regulation and product code for the TACHAS (Refer to Section 4 – **Scope)**. In addition, other sections of this special controls 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 TACHAS and lead to a timely premarket notification [510(k)] review and clearance. 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 other FDA documents on this topic, such as the **510(k) Manual - Premarket Notification: 510(k) - Regulatory Requirements for Medical Devices**, http://www.fda.gov/cdrh/manual/510kprt1.html.

Under "**The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications; Final Guidance**[2]," 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 special controls guidance document has been issued. Manufacturers considering modifications to their own cleared devices may lessen the regulatory burden by submitting a Special 510(k).

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 statutory and regulatory criteria in the manner suggested by the guidance and in your attempt to 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**" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html.

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 controls 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 guidance document, as well as any additional risks specific to your

[2] http://www.fda.gov/cdrh/ode/parad510.html

device. This section suggests information to fulfill some of the requirements of 807.87 as well as some other items that we recommend you include in an Abbreviated 510(k).

Coversheet

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

Proposed labeling

Proposed labeling should be sufficient to describe the device, its intended use, and the directions for its use. (Refer to Section 10 for specific information that should be included in the labeling for devices of the types covered by this document.)

Summary report

We recommend that the summary report contain:

- A 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.[3]

- A description of device design requirements.

- An identification of the Risk Analysis method(s) used to assess the risk profile in general as well as the specific device's design and the results of this analysis. (Refer to Section 6 for the risks to health generally associated with the use of this device that FDA has identified.)

- Discussion of 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.

- A brief description of the test method(s) you have used or intend to use to address each performance aspect identified in Sections 6 and 7 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.)

[3] Refer to http://www.fda.gov/cdrh/ode/indicate.html 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

If any part of the device design or testing relies on a recognized standard, you 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.[5] Please note that testing must be completed before submitting a declaration of conformity to a recognized standard. (21 USC 514(c)(2)(B)). For more information refer to the FDA guidance, **Use of Standards in Substantial Equivalence Determinations; Final Guidance for Industry and FDA**, http://www.fda.gov/cdrh/ode/guidance/1131.html.

If it is not clear how you have addressed the risks identified by FDA or 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 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 for a TACHAS.

4. Scope

The scope of this document is limited to the following devices as described in 21 CFR 874.3340 (product code: NIX).

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

> Transcutaneous Air Conduction Hearing Aid System (TACHAS) is a wearable sound-amplifying device intended to compensate for impaired hearing without occluding the ear canal.

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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), http://www.fda.gov/cdrh/ode/reqrecstand.html.

The device consists of an air conduction hearing aid attached to a surgically fitted tube system, which is placed through soft tissue between the post auricular region and the outer ear canal.

5. Risks to Health

In the table below, FDA has identified the risks to health generally associated with the use of the TACHAS 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, prior to submitting your 510(k), to identify any other risks specific to your device. 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 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
Infection/Local Inflammation	Sections 7, 8, 9, 10
Injury to Ear Canal	7, 9, 10
Ineffective Amplification	6, 9, 10

6. Bench Testing

You should test the electroacoustic characteristics of the air conduction hearing aid according to ANSI S3.22: Specification of Hearing Aid Characteristics. Further, real ear probe microphone testing of the TACHAS should be evaluated in accordance with ANSI S3.42: Testing Hearing Aids with a Broad-Band Noise Signal.

7. Materials Specification

We recommend that you include a brief summary of the fatigue testing and strength test validation of the tube system, including the tube, coupling mechanism, and hearing aid connection.

8. Biocompatibility and Sterility

All tissue contacting materials should be biocompatible. Further, the tube should be sterile with a sterility assurance level of 1×10^{-6}. We recommend that you evaluate the biocompatibility of all tissue contacting materials in your device. Please refer to the guidance document entitled **Blue Book Memo, G95-1, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"** http://www.fda.gov/cdrh/g951.html. For information regarding the sterility of components, please refer to **Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA,** http://www.fda.gov/cdrh/ode/guidance/361.html.

You should select biocompatibility tests appropriate for tissue and bone 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.

9. Clinical Information

In accordance with the Least Burdensome provisions of the FDA Modernization Act of 1997, 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 will not be needed for most TACHAS, FDA may recommend that you collect clinical data for a TACHAS with:

- designs dissimilar from designs previously cleared under a premarket notification;
- new technology, i.e., technology different from that used in legally marketed TACHAS devices; or
- indications for use dissimilar from legally marketed TACHAS devices.

FDA will always consider alternatives to clinical testing when the proposed alternatives are supported by an adequate scientific rationale. Please consider contacting the Ear, Nose, and Throat Devices Branch to discuss any clinical testing before initiating studies.

You should address the above differences with clinical information obtained from use of your TACHAS in the patient population described in the "Indications for Use" section of your device labeling. FDA believes that you should include clinical data on at least 30 patients implanted with your TACHAS who have been followed for a minimum of 6 months post- implantation in order to demonstrate that clinical performance will meet users' needs. We recommend that you also present clinical data on a subset of these patients who have been followed for a minimum of 1 year to evaluate longer-term complications with your device (e.g., granulation tissue, inflammation). Alternative length of follow-up may be also considered.

We recommend that you include the following clinical information:

Demographic Data

We recommend that you provide:

- age
- sex
- type and severity of hearing loss.

Surgical Complications

We recommend that you describe all complications (e.g., bleeding, ear injury, infection), immediate and late, associated with the surgical implantation procedure.

Other Adverse Events

We recommend that you describe all adverse events associated with the implanted conduction tube. The description should include:

- type of event
- known contributing factors (if any)
- time of the event relative to implantation
- frequency of the event over time
- treatment and outcome of the event.

Pre- and Post-Operative Audiological Data

Because the design of TACHAS devices mitigates hearing loss differently than air-conduction hearing aids, (i.e., the microphone is behind the ear and the system does not occlude the ear canal), we recommend that you submit complete audiological data for each subject, including preoperative and postoperative audiological assessments and hearing aid evaluations. In particular, we recommend that you describe and provide the aided performance assessment, including, as appropriate:

- functional gain testing
- real ear probe microphone testing
- tolerance levels
- speech perception measures
- microphone placement effects of the TACHAS.

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 812.[6] FDA has determined that the TACHAS addressed by this guidance document is a non-significant risk device, therefore the study is subject to the abbreviated requirements of 21 CFR 812.2(b).[7] 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).

After FDA determines that the device is substantially equivalent, clinical studies conducted in accordance with the indications reviewed in the 510(k), including clinical design validation studies conducted in accordance with the quality systems regulation, are exempt from the investigational device exemptions (IDE) requirements. However, such studies must be performed in conformance 21 CFR Part 56 and 21 CFR Part 50.

[6] Clinical trials are exempt from 21 CFR 801.420 and 21 CFR 801.421.

[7] Refer to Blue Book Memorandum entitled "SIGNIFICANT RISK AND NONSIGNIFICANT RISK MEDICAL DEVICE STUDIES " at http://www.fda.gov/cdrh/d861.html.

10. 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 807.87(e).[8]

Directions for use

As a prescription device, the TACHAS is exempt from having adequate directions for lay use. Nevertheless, under 21 CFR 807.87(e), we expect to see 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 who are trained in otologic surgery with the features of the device and how to use it in a safe and effective manner.

User Instructional Brochure

We recommend that the User Instructional Brochure, required under 21 CFR 801.421, include the following information, in addition to the information required under 21 CFR 801.420.

A statement encouraging patients to consider an evaluation of conventional hearing aid(s) prior to considering implantation of the TACHAS, given the surgical risks and post-operative complications associated with the TACHAS.

A detailed explanation of realistic expectations of the TACHAS compared to the performance of a conventional hearing aid.

A clear description of the type and frequency of surgical risks, in layman's terms, associated with implantation of the TACHAS.

A summary of local inflammatory and infectious complications associated with the implanted conducting tube over time. The summary should include the type, frequency, treatment, and outcome of these complications based on the clinical information gathered in Section 9 of this document.

Clinical experience to date with the implanted sound conducting tube demonstrates the importance of local wound care and personal hygiene practices in preventing local infectious and inflammatory complications. Therefore, we recommend that you include a detailed description of these practices (e.g., cleaning the area with hydrogen peroxide, application of antibiotic ointments, hand

[8] Although final labeling is not required for 510(k) clearance, final labeling must also comply with the requirements of 21 CFR 801 before a medical device is introduced into interstate commerce. Because the TACHAS includes an air conduction hearing aid component, the labeling must conform to the labeling requirements and conditions for sale described in 21 CFR 801.420 and 21 CFR 801.421. 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.

washing prior to tube manipulation) necessary to mitigate these complications. We recommend that the User Instructional Brochure also indicate signs and symptoms that require consultation with the implanting surgeon (e.g., bleeding, granulation tissue around the tube, any fluid draining from the ear, near the tube or from the tube itself).

Physician Labeling

We recommend that the physician labeling (Surgeon's Guide) include the following information.

The surgeon performing the procedure should have training and experience in otologic surgery.

The age, audiological, and health status criteria defining the appropriate patient population for fitting with the TACHAS.

A statement recommending that patients be fully informed regarding an evaluation of conventional hearing aid(s) prior to considering implantation of the TACHAS, given the surgical risks and post-operative complications associated with the TACHAS.

A clear description of the type and frequency of surgical risks (immediate and delayed) associated with implantation of the TACHAS and recommendations to minimize these risks.

A summary of local inflammatory and infectious complications associated with the implanted conducting tube over time. The summary should include the type, frequency, treatment, and outcome of these complications based on the clinical information gathered in Section 9.

Contraindications, e.g., aural keloids, chronic otitis externa.

A clear description of the components of the TACHAS as well as the instrumentation used during the insertion procedure.

An illustrated description of the technique for local anesthesia, placement of the post-auricular incision, creation of the soft tissue tract, sizing of the tube to fit the patient, and insertion of the tube.

Instructions for removal of the TACHAS should it be necessary for medical reasons or desired by the patient.

Detailed instructions for post-operative care, including recommended followup visits, wound dressings, application of topical antibacterial agents, and recommendations regarding bathing and hair washing during healing of the tract.

Instructions for counseling patients on the importance of ongoing local wound care and hygiene practices (e.g., cleaning the area with hydrogen peroxide, application of antibiotic ointments, hand washing prior to tube manipulation) necessary to mitigate the infectious/inflammatory complications associated with the implanted sound conducting tube.