



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 20 2002

David J. Navaroli, Jr.
President
Auric Hearing Systems, Inc.
6000 Fairview Avenue, Suite 1200
Charlotte, NC 28210

Re: K013298 RetroX
Automatic Evaluation of Class III Designation
Regulation Number: 21 CFR 874.3340
Regulation Name: Transcutaneous Air Conduction Hearing Aid System (TACHAS)
Regulatory Class: Class II
Product Code: NIX

Dear Mr. Navaroli:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your petition for classification of the RetroX that is intended to compensate for impaired hearing without occluding the ear canal. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the RetroX (and substantially equivalent devices of this generic type) into class II under the generic name, Transcutaneous Air Conduction Hearing Aid System (TACHAS). This order also identifies the special controls applicable to this device. FDA identifies this generic type of device as:

A wearable sound-amplifying device intended to compensate for impaired hearing without occluding the ear canal. 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.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the act), devices that were not in commercial distribution prior to May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976 (the amendments)), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the FDA regulations (21 CFR 807).

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Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) for a device may, within 30 days after receiving an order classifying the device into class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request classify the device. This classification shall be the initial classification of the device type. Within 30 days after the issuance of an order classifying the device type, FDA must publish a notice in the Federal Register classifying the device type.

On June 21, 2002, FDA filed your petition requesting classification of the RetroX into class II. The petition was submitted under section 513(f)(2) of the act. In accordance with section 513(f)(1) of the act, FDA issued an order on May 24, 2002, automatically classifying the RetroX into class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, which was subsequently reclassified into class I or class II. In order to classify the RetroX into Class II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the petition, FDA has determined that the RetroX intended to compensate for impaired hearing without occluding the ear canal can be classified into class II with the establishment of special controls. FDA believes that class II special controls, along with the general controls of the act, provide reasonable assurance of the safety and effectiveness of the device. Therefore, in addition to the general controls of the act, the RetroX is subject to the following special controls: Class II Special Controls Guidance Document: Transcutaneous Air Conduction Hearing Aid System (TACHAS); Guidance for Industry and FDA.

This Class II Special Controls Guidance Document identifies the potential risk presented by the device as follows:

1. Infection /local inflammation;
2. Injury to the ear canal; and
3. Ineffective amplification.

FDA believes the following controls identified in the Class II Special Controls Guidance Document for a TACHAS when combined with the general controls of the act, will provide reasonable assurance of the safety and effectiveness of this type device:

1. Electro-acoustic testing;
2. Fatigue testing;
3. Strength test validation;

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4. Biocompatibility;
5. Sterility;
6. Clinical information; and
7. Labeling to include prescription labeling in accordance with 21 CFR 801.109.

Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device and, therefore, the device is not exempt from the premarket notification requirements. The device is used as a wearable sound-amplifying device intended to compensate for impaired hearing without occluding the ear canal. FDA review of key design features, data sets from bench studies and clinical trials, other relevant performance data, and labeling will ensure that acceptable levels of performance for both safety and effectiveness are addressed before marketing clearance. Thus, persons who intend to market this device type must submit to FDA a premarket notification submission containing information on the TACHAS they intend to market prior to marketing the device.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market this device, subject to the general control provisions of the Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Eric Mann, M.D., Ph.D. or Teri Cygnarowicz, M.A., CCC-A at (301) 594-2080.

Sincerely,



Daniel G. Schultz, M.D.
Deputy Director for Clinical and
Review Policy
Office of Device Evaluation
Center for Devices and
Radiological Health