



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 1 2004

Micro-Ear Technology, Inc.
c/o Deborah Shaffer
Regulatory Team Leader
3500 Holly Lane North
Suite 10
Plymouth, MN 55447

Re: K041302
Trade/Device Name: Refuge Tinnitus Masker Sound Generator
Regulation Number: 21 CFR 874.3400
Regulation Name: Tinnitus masker
Regulatory Class: Class II
Product Code: KLW
Dated: May 13, 2004
Received: May 17, 2004

Dear Ms. Shaffer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041302

Device Name: Refuge Tinnitus Masker

Indications For Use:

The Refuge Tinnitus Maskers styles are In-The Canal and Behind-The-Ear that are electronic; air-conduction broadband noise generator intended to generate noise of sufficient intensity and bandwidth to be used for tinnitus masking therapy. The Refuge Tinnitus Masker is intended for those individuals who experience tinnitus, and do not need or desire amplification. The intended use of this device includes it's fitting by a qualified audiologist or other hearing healthcare professional familiar with the diagnosis and treatment of tinnitus

The target population is the adult population over 18 years of age.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Karen H. Breen
(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devices

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