DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 8 2001

ADM Tronics Unlimited, Inc.
c/o James E. Lenick, Esq.
FDA Counsel to ADM Tronics, Inc.
P.O. Box 2002
118 Henry Street
Morristown, TN 37814

Re: 510(k) Number: K981704
Trade/Device Name: Aurex - 3 Tinnitus Masker
Regulation Number: 21 CFR 874.3400
Regulatory Class: Class II
Product Code: KLW
Dated: June 26, 1998
Received: June 29, 1998

Dear Mr. Lenick:

This letter corrects our substantially equivalent letter of August 5, 1998, regarding the Aurex - 3 Tinnitus Masker. The review forms incorrectly noted this device as over-the-counter (OTC) without requiring a prescription for use. However, tinnitus maskers are Class II prescription devices. The intended use statement did not mention OTC, nor was there any reference to OTC in any other part of the 510(k) submission. Also, the listed predicate device was a prescription device.

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

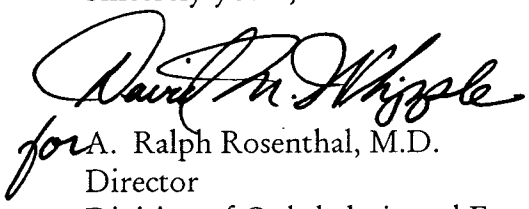
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirements, as set forth in the Quality System Regulation

(QS) for Medical Devices: General (QS) regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to continue marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



for 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

510(k) Number (if known): K981704

Device Name: AUREX-3

Indications for Use:

For use in treatment and control of tinnitus.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Perscription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter use ____

(Optional Format 1-2-96)

James K. Rowe, Ph.D.
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K981704