K061111

16 2006

Attachment 5

510(k) SUMMARY

Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes Tinnitus Control, Inc.'s summary for the Tinnitus Phase-Out.

SUBMITTER'S NAME	Tinnitus Control, Inc.
ADDRESS:	66 East 80th Street, Suite 1A New York, New York 10021
CONTACT PERSON	Calvin Yee
TELEPHONE NUMBER	212-535-6160 (official number)
FAX NUMBER:	212-517-3728
DATE OF SUBMISSION	April 20, 2006

1. **Identification of device**

   Proprietary Name: Tinnitus Phase-Out
   Common Name: Tinnitus Masker
   Classification Status: Class II per Regulation §874.3400
   Product Code: KLW – Tinnitus Masker.

2. **Equivalent device**

   Tinnitus Rx – K030791.

3. **Description of the Device**

   The device description of the Tinnitus Phase-Out is as follows:

   The Tinnitus Phase-Out consists of a personalized sound recorded onto a patient treatment device. The recorded sound is equivalent to that generated by the Tinnitus Rx. Performance testing demonstrating this equivalence is presented in the 510(k).

   The treatment regimen for the Phase-Out is identical to that of the Rx. The only difference is the use of a patient treatment device instead of a customized CD.

4. **Intended Use**

   The Tinnitus Phase-Out's intended use is to provide temporary relief of tinnitus symptoms. This is the **same intended use** as previously cleared for the Tinnitus Rx, K030791.

5. Discussion of Performance Testing

Bench testing demonstrating audio equivalence has been provided in the 510(k). Additionally, the following have been met:

- UL electrical certification
- FDA Guidance describing Special 510(k)s: The New 510(k) Paradigm
- Class II Special Control Guidance, 21 CFR 874.3400(b)
- Conformance to the EU Medical Device Directive..

6. Conclusion

In summary, the Tinnitus Phase-Out described in the submission is substantially equivalent to the predicate device, the Tinnitus Rx. The Tinnitus Phase-Out is substantially equivalent to the device already on the market, and presents no new concerns about safety and effectiveness. Additionally, the new device has identical indications to the predicate device, and the labeling is consistent both with FDA guidance as well as current medical practice.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 16 2006

Tinnitus Control, Inc.
c/o Russell P. Pagano, Ph.D.
M Squared Associates, Inc.
719 A Street, NE
Washington, DC 20002

Re: K061111
Trade/Device Name: Tinnitus Phase-Out
Regulation Number: 21 CFR 874.3400
Regulation Name: Tinnitus masker
Regulatory Class: Class II
Product Code: KLW
Dated: April 20, 2006
Received: April 21, 2006

Dear Dr. Pagano:

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.

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) 827-8910. 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/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2

Indications for Use Statement

510(k) Number (if known) K061111

Device Name Tinnitus Phase-Out

Indications For Use The Tinnitus Phase-Out is intended to provide the temporary relief of tinnitus symptoms.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K061111