



SEP 17 2003

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Starkey Laboratories, Inc.  
c/o Scott LaPointe  
Regulatory Affairs Coordinator  
6700 Washington Ave. South  
Eden Prairie, MN 55344

Re: K030180  
Trade/Device Name: Crescent Sound Generator  
Regulation Number: 21 CFR 874.3400  
Regulation Name: Tinnitus masker  
Regulatory Class: Class II  
Product Code: KLW  
Dated: September 4, 2003  
Received: September 5, 2003

Dear Mr. LaPointe:

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) 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 handwritten signature in cursive script that reads "A. Ralph Rosenthal".

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): K030180

Device Name: Crescent Sound Generator

Indications For Use:

The Crescent Sound Generator is an electronic, air-conduction broadband noise generator intended to generate noise of sufficient intensity and bandwidth to be used for tinnitus masking therapy. The Crescent Sound Generator is intended to be used by 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.

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

---

Concurrence of CDRH, Office of Device Evaluation (ODE)



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

(Optional Format 3-10-98)

510(k) Number K030180