

K913880

SUMMARY OF SAFETY AND EFFECTIVENESS JAN 12 1998

The Sonix Hearing Aid Fitting and Programming System is a hand-held, battery-powered, portable device used to fit and program Sonix hearing aids and to store certain patient data. The Sonix Hearing Aid Fitting and Programming System is substantially equivalent to the *microfit@microtouch™ programming system* by Micro-Tech [510(k) No. unknown] and the ReSound Portable Prescriptive Programming System® [510(k) No. K931372]. Substantial equivalence to the predicate devices, is based on the following:

- The intended use is the same, i.e., the Sonix Hearing Aid Fitting and Programming System is a lightweight hand-held device intended to fit and program Sonix hearing aids. It also provides database storage of patient identification and audiologic information.
- The device is lightweight and fully portable.
- Standard batteries power the device.
- The microcomputer base meets FCC and CE-Marking requirements.
- The System displays the frequency response, gain and output characteristics of the hearing aid type being programmed.
- No software installation is required on the part of the dispenser.
- The level of concern for the software is **MINOR**.
- The Sonix Hearing Aid Fitting and Programming System does not raise new issues of safety or effectiveness.

In conclusion, the Sonix Hearing Aid Fitting and Programming system described in this submission is substantially equivalent, i.e., has the **SAME** intended use and does not raise different questions regarding safety and effectiveness, to the Micro-Tech *microfit@microtouch™ programming system* and the ReSound Portable Prescriptive Programming System® [510(k) No. K931372].



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 12 1998

Jeannette Sejoover Johnson, Ph.D.
Vice President, Research and Planning
Sonix Technologies, Inc.
5330 South 900 East, Suite 240
Salt Lake City, Utah 84117-7261

Re: K973880
Sonix Hearing Aid Fitting and
Programming System
Dated: October 13, 1997
Received: October 14, 1997
Regulatory class: I
21 CFR 874.3300/Procode: 77 ESD

Dear Dr. Johnson:

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 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 (Pre-market 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 Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, 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 begin 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsmamain.html>.

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K973880

Device Name: THE SONIX HEARING AID FITTING & PROGRAMMING SYSTEM

Indications For Use:

The Sonix Hearing Aid Fitting and Programming System is a lightweight hand-held battery-powered device intended for use in fitting and programming Sonix hearing aids using individual patient audiogram and/or loudness data. It also provides database storage of patient identification information, audiogram, loudness information and hearing aid selection and fitting parameters.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David R. Segerson
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K973880

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use