K982878

NOV 3 1998

510 (K) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter's Name: Micro Audiometrics Corp.
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South Daytona, FL 32119

Contact Person: Patricia L. Travis
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Date Prepared: August 11, 1998

Device Name: Classification Name - Audiometer
Common/Usual Name - Air Conduction, bone conduction, and speech audiometer
Proprietary name - Earscan 3

Predicate Device: Micro Audiometrics Corp. Earscan (K812529)
Micro Audiometrics Corp. Earscan II (K812529)
Decibel Instruments, Inc. ProDigit 2000 (K940999)

Device Description, Intended Use & Effectiveness:

The Earscan 3 is similar to and predicated upon the Micro Audiometrics Corp. Earscan and Earscan II, and Decibel Instruments, Inc. ProDigit 2000. Earscan 3 is a computer peripheral whose purpose is to test the condition of the auditory pathway through manual and automatic air conduction audiometry, bone conduction audiometry and speech audiometry. Earscan 3 is a lower level of concern device and is intended to be used by trained personnel in the industrial, school and medical environment.

Safety:

The design of Earscan 3 provides electrical safety to the patient and the user. Earscan 3 intends to meet electrical standards IEC 601-1.1992 and UL2601. The wall cube will comply with UL2601-1. To prevent the unlikely possibility of excessive exposure to high-level sounds, a firmware check was implemented which limits the maximum duration of continuous tones. The software also prevents the generation of a hearing level greater than specified by ANSI S3.6-1996 Type 3C audiometer and IEC 60645 Type 3 audiometer. In complying with USB Spec. 1.0, Earscan 3 will not interfere with other devices in its computer environment. With respect to mechanical safety, the air conduction headphone and headband comply with ANSI S3.6, and the bone conduction vibrator and headband comply with ANSI S3.6.

Summary of Effectiveness:

Micro Audiometrics Corporation's Earscan 3 is a combination of three predicate audiometer devices into one computer interfaced audiometer equivalent or superior in effectiveness to its predicates in testing the auditory pathway.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 3 1998

Jason R. Keller
President
Micro Audiometrics Corp.
2200 So. Ridgewood Ave., US#1
South Dayton, FL 32119-3018

Re: K982878
Earscan 3
Dated: August 11, 1998
Received: August 14, 1998
Regulatory class: II
21 CFR 874.1050/Procode: 77 EWO

Dear Mr. Keller:

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 (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 Current Good Manufacturing Practice requirements, 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/dsma/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): K982878

DEVICE NAME: Earscan 3

INDICATIONS FOR USE:

Earscan 3 is a peripheral used with a computer that creates an air conduction, bone conduction and speech audiometer, as defined by the standards shown in the labeling of the About Screen and the Splash Screen of the Earscan 3 software.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use ____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K982878