K973320

SECTION 2
510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

NOV 25 1997

Submitter's Name: Decibel Instruments, Inc.
3857 Breakwater Ave.
Hayward, CA 94545 USA
Telephone: (510) 264-4330
Contact Person: Adnan Shennib, Chief Technical Officer

Date of Summary: August 29, 1997

Device Name: Articulate Fitting System™

Device Classification: Audiometer (77 EWO); 21 CFR § 874.1050

Legally Marketed Predicate Devices: The legally marketed predicate devices are:

- The Decibel Instruments ProDigit 2000™ Personal Digital Audiometer (K940999), determined to be substantially equivalent to a legally marketed (preAmendment) device on April 22, 1994, and
- The Madsen Electronics RH2000 Real Ear Measurement System (K945199), determined to be substantially equivalent to a legally marketed (preAmendment) device on April 11, 1995.

Device Description: The Articulate Fitting System™ is used with the Decibel Instruments ProDigit 2000™ Personal Digital Audiometer for audiometric testing, real ear measurements, and fitting and programming the commercially available Decibel Instruments Articulate Hearing Devices. The System has four main components:

- The legally marketed Decibel Instruments ProDigit 2000™ Personal Digital Audiometer, a computer-based audiometry system;
- The Decibel Instruments IntraCanal Probe™ (ICP), a transducer placed in the ear canal for audiometric testing;
- The Decibel Instruments IntraCanal Probe™ Interface, which provides the communication link between the ICP and the ProDigit 2000™ Audiometer and allows real ear measurements; and
- The commercially available HI-PRO hearing aid programmer with the Articulate Fitting software utilizes automated fitting algorithms and visual tools to program the Articulate Hearing Devices following audiometric evaluation.

Intended Use: The Articulate Fitting System™ is used with the ProDigit 2000™ Personal Digital Audiometer to fit and program Articulate Hearing Devices. The ProDigit 2000™

Audiometer produces controlled levels of test tones and signals intended for use in conducting diagnostic hearing evaluations and assisting in the diagnosis of possible otologic disorders.

Descriptive Summary Of Technological Characteristics And Those Of Predicate Devices: The ProDigit 2000™ Personal Digital Audiometer is a computer-based instrument used to evaluate human hearing function and to assist in the diagnosis of possible otologic disorders. The audiometer is typically used by trained and qualified audiologists or other audiometric professionals. The instrument generates audio stimuli having various acoustic properties in order to elicit responses from the test subject; the responses are used to assess hearing function. Typical stimuli consist of pure tones, speech, and masking signals which are delivered to the ear via acoustic couplers, or transducers.

The Articulate Fitting System™ is indicated for use with the ProDigit 2000™ Personal Digital Audiometer to conduct audiometric evaluation, and to fit and program Articulate Hearing Devices. In addition to the features of the ProDigit 2000™ Audiometer, the Articulate Fitting System provides programming capabilities (including auto-fit calculations) for Decibel Instruments Articulate programmable hearing instruments when used with the commercially available HI-PRO Universal Hearing Aid programmer. The Articulate Fitting System also provides individualized fitting capabilities and subjective testing for fit of all Decibel Instruments Articulate hearing instruments, both non-programmable and programmable models. Other features include real ear measurements and dB SPL audiometry using the IntraCanal Probe (ICP).

The Madsen Electronics RH2000 Real Ear Measurement System (Aurical) is a computer-based instrument used to evaluate human hearing function and to assist in the diagnosis of possible otologic disorders. In addition to standard audiometric capabilities, the Aurical provides programming capabilities for programmable hearing instruments when used with the commercially available HI-PRO Universal Hearing Aid programmer, as well as subjective testing for fit of hearing instruments. Other capabilities include real ear measurements, noise signals testing, auditory area mapping and hearing instrument evaluation.

Performance Data: Testing was conducted by Decibel Instruments, Inc. to evaluate the electroacoustic performance of the IntraCanal Probe (ICP). The frequency response, linearity, and maximum undistorted acoustic output versus constant voltage input and frequency were measured. The ICP demonstrated a smooth, well-defined acoustic frequency response within specified limits, and the response was linear below the maximum undistorted acoustic output levels. When used in accordance with the labeling, the ICP can be expected to deliver accurate acoustic stimuli for performing audiometric testing.

Conclusion: The information and data provided in this 510(k) Notification establish that the Articulate Fitting System™ used with the ProDigit 2000™ Personal Digital Audiometer is substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Lisa S. Jones, R.A.C.
Regulatory Affairs Consultant
Decibel Instruments, Inc.
c/o Devices for the Future, LLC
9223 Ilona Lane
Houston, TX 77025-4218

Re: K973320
Articulate Fitting System (Audiometer)
Dated: August 29, 1997
Received: September 3, 1997
Regulatory Class: II
21 CFR 874.1050/Procode: 77 EWO

NOV 25 1997

Dear Ms. Jones:

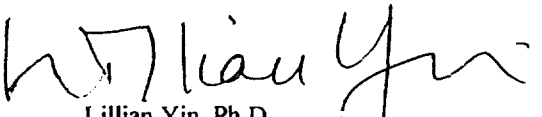
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 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): K973320

Device Name: ARTICULATE HEARING SYSTEM

Indications For Use:

Intended Use: The Articulate Fitting System™ is used with the ProDigit 2000™ Personal Digital Audiometer to fit and program Articulate Hearing Devices. The ProDigit 2000™ Audiometer produces controlled levels of test tones and signals intended for use in conducting diagnostic hearing evaluations and assisting in the diagnosis of possible otologic disorders.

(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 Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K973320

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)