K984518

SONIC innovations

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

for the

SONIC INNOVATIONS® COMPLETELY-IN-THE-CANAL (CIC) DSP HEARING AID

Prepared: December 10, 1998

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Classification Name:	Hearing Aid – Air Conduction
Common/Usual Name:	Hearing Aid
Proprietary Name:	*SONIC innovations®* Completely-in-the-Canal DSP Hearing Aid with Soft Shell
Device Type:	Completely-in-the-Canal (CIC) Hearing Aid
Classification:	Hearing Aid, Air Conduction Panel 77, Procode ESD, 874.3300, Class I
Intended Use:	This air conduction hearing instrument is intended to amplify sound pressure waves and transmit the signal to the external ear through the medium of air to compensate for hearing losses of mild to moderate degree.
Indications for Use	Indications for use include persons with mild to moderate hearing impairment depending upon specific characteristics of the hearing loss and the patient's environmental situations.
Substantially Equivalent to:	The *SONIC innovations* Completely-in-the-Canal DSP w/ Soft Shell is substantially equivalent to the *SONIC innovations®* CIC DSP hearing aid [510(k) not required], the Decibel Instruments Articular (inTune™) Hearing Aids [510(k) No. K964603], and the Hearing Components Ad-Hear *Comply Disposable Earmolds* [510(k)915794], i.e., it has the SAME intended use and does not raise different questions regarding safety and effectiveness.

Materials:	Assembled from standard hearing aid components mounted with custom microchips. The hearing aid soft shell is manufactured from biocompatible materials that have been used in other medical devices.
Technical Characteristics:	Technical specifications are in accordance with ANSI S3.22 1987.
Power source:	Standard Zinc-Air hearing aid battery, size 10.
Features:	The *SONIC innovations* Completely-in-the-Canal DSP Hearing Aid with Soft Shell is a programmable hearing aid with fully digital signal processing and full dynamic range multiband compression (*multiplicative DSP™)* that allows independent adjustment of gain and compression characteristics within each frequency band from 250 to 8000 Hz. The *SONIC innovations* hearing aid provides database storage of patient information and hearing aid fitting parameters. The Soft Shell is removable and/or replaceable, and can be cleared or replaced as needed. The shells are offered in a few basic sizes and selected by the hearing aid dispenser.
Assembly:	Except for the Soft Shell, the device is manufactured and delivered completely assembled to the hearing aid dispenser using materials and techniques widely used by other manufacturers of hearing devices. Two versions of the Soft Shell are available, both made of biocompatible materials. The two versions of the shell are available in multiple sizes, the specific one being selected by the hearing aid dispenser as suitable for an individual patient. The Soft Shell may be cleaned and/or replaced as needed by either the hearing aid dispenser or the individual patient.
User Controls:	None
Programmability:	All parameters are digitally programmed via proprietary software and the *SONIC innovations* Hearing Aid Fitting and Programming System or HI-Pro/Noah with PC or HI-Pro with PC.

A USER'S INSTRUCTION GUIDE AND ANSI TECHNICAL DATA ARE SUPPLIED WITH EACH HEARING AID.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 12 1999

Jeannette Seloover Johnson, Ph.D.
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Re: K984518
SONIC Innovations® Completely-in-the Canal (CIC) DSP Hearing Aid with Soft Shell
Dated: December 10, 1998
Received: December 21, 1998
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 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). 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,

CAPT Daniel G. Schultz, M.D.
Acting 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): K984518

Device Name: Sonic Innovations Completely-In-The-Canal DSP Hearing Aid with Soft-Shell

Indications For Use:

A. General Indications:

The indication for use of the air conduction hearing aids in this submission is to amplify sound for individuals with impaired hearing. The devices are indicated for individuals with losses in the following category(ies). (Check appropriate space(s)):

Severity:	Configuration:	Other
✓ 1. Slight	✓ 1. High Frequency - Precipitously Sloping	✓ 1. Low tolerance to [illegible]
✓ 2. Mild	✓ 2. Gradually Sloping	2.
✓ 3. Moderate	✓ 3. Reverse Slope	3.
4. Severe	✓ 4. Flat	
5. Profound	5. Other	

B. Specific Indications (Only if appropriate.):
(Most psychoacoustic indications such as improved speech intelligibility in background noise, must be supported by clinical data.)

1.

2.

3.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lepmann

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K984518

Restricted device (per 21 CFR 801.420 & 21 CFR 801.421)