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K021867

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.

Submitter's Name: InSound® Medical, Inc.
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Date of Summary: June 4, 2002
Revision Date: November 12, 2002
2nd Revision Date: November 18, 2002

Legally Marketed Devices To Which Equivalence is Claimed: The legally marketed predicate devices to which equivalence is claimed are:

- The Songbird Disposable Hearing Aid, legally marketed in 2000, after the exemption of hearing aids from 510(k) Notification, effective February 19, 1998.
- The Decibel Articulate (K964603), determined to be substantially equivalent to a pre-enactment device on December 6, 1996.
- The Philips XP Series (K921725), determined to be substantially equivalent to a pre-enactment device on August 11, 1992.

Device Description: The InSound XT Series Hearing Device amplifies and delivers sounds via air conduction to the external ear of persons with hearing loss. The microphone transforms sound waves into electrical signals and delivers it to the hearing aid circuit, which is powered by the battery. The hearing device is extended-wear (up to 4 months) and disposable. It is placed deep in the ear canal by an ENT physician. The amplification characteristics are contained in digitally programmable memory and adjustment of device parameters is achieved through the proprietary HandFit™ Fitting System and Software.

Intended Use: The InSound XT Hearing Device is a disposable, extended-wear, air conduction hearing aid, designed to be used and worn by hearing-impaired persons. The intended use of the InSound XT Hearing Device is essentially identical to that of the legally marketed predicate devices. Hearing assistance is achieved through amplification of sound pressure waves, which are transmitted to the external ear canal via air conduction. The hearing aid is placed in the ear canal by an ENT physician and it can remain in the ear canal for up to 4 months or until the battery is depleted. Upon device removal, the hearing aid is discarded.

Descriptive Summary of Technological Characteristics and Those of Predicate Devices: The InSound XT Hearing Device is a disposable, extended-wear, air-conduction, programmable hearing aid with a deep canal fitting. It is placed in the ear canal by an ENT physician and it is worn continuously for up to 4 months. The hearing aid's receiver is located deep in the canal, around the second bend, transmitting sound to the tympanic membrane. These characteristics are similar to the Philips XP Series. Amplification characteristics are contained in digitally programmable memory delivered through programming, as with the Decibel Articulate Hearing Aid. The InSound XT Hearing Device is fit to the user with integrated soft retaining seals, like the Songbird Disposable Hearing Aid. Like both the Decibel and Songbird Hearing Aids, the size of the soft retaining seals is selected from a stock of available sizes. The custom battery of the InSound XT Hearing Device is integrated in the device and has a long life. In addition, the hearing aid is discarded when the battery is depleted. Those characteristics are similar to the Songbird Disposable Hearing Aid.

Performance Data: The InSound XT Series hearing device was evaluated for safety and efficacy in the laboratory and in clinical trials with human subjects.

The device has been evaluated to ensure that the long-term residency in the ear canal is safe for the device user. All materials contacting the skin meet USB Class 6 requirements and additionally passed testing for antimicrobial, cytotoxicity, irritation and sensitization.

The device with its battery has been assessed as per ANSI C18 Part 1-1999 and passed well within the specifications.

The performance characteristics of the XT Series hearing aid have been evaluated in accordance with ANSI S3.22-1996, "Specification of Hearing Aid Characteristics". The devices met all applicable specifications developed by the manufacturer in accordance with test methods outlined in the specifications.

Clinical trials for the InSound XT devices have confirmed that the hearing aids are comfortable, safe and efficacious for wear in human subjects. The Clinical results were obtained in three parts: (1) feasibility of the devices in-situ, (2) comfort and long-term wear of the devices and (3) functional device studies which demonstrated user benefit during extended wear via a hearing aid verification battery. Additionally, the clinical trials validated the safe and effective use of the InSound XT accessories and the wireless hand-held fitting system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 9 2002

InSound Medical, Inc.
c/o Susan Whichard
37500 Central Court
Newark, CA 94560

Re: K021867
Trade/Device Name: InSound XT Series
Regulation Number: 21 CFR 874.3300
Regulation Name: Hearing Aid
Regulatory Class: Class I
Product Code: ESD
Dated: September 30, 2002
Received: October 1, 2002

Dear Ms. Whichard:

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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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. 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

Date of submission: June 4, 2002
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510(k) Number: K021867

Device Name: InSound XT Series Hearing Aid

Indications for Use: The InSound XT Hearing Aid is a disposable, extended-wear, air conduction hearing aid, designed to be used and worn by hearing-impaired persons. Hearing assistance is achieved through amplification of sound pressure waves, which are transmitted to the external ear canal via air conduction. The hearing aid is placed in the ear canal by an ENT physician and it can remain in the ear canal for up to 4 months or until the battery is depleted. Upon device removal, the hearing aid is discarded.

Prescription Use ✓
(Per 21 CFR 801.109)

Karen A Baker
(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K021867