K081136

510(K) Summary

MAY - 8 2008

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

Contact Person: Susan Whichard (VP of Marketing)
Insound Medical, Inc.
39660 Eureka Drive
Newark, CA 94560 USA
Telephone: (510) 792-4000, ext 450
Fax: (510) 792-4050

Reason for 510(k) Submission: Change in Indications for Use
Device Trade Name: Lyric
Device Classification Name: Hearing Aid, Air Conduction: 77 ESD; 21 CFR 874.3300
FDA Establishment Registration Number: 3003793405
Owner / Operator Number: 9051571

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 marketing in 2000, after the exemption of hearing aids from 510(k) Notification, effective February 19, 1998.
- The Decibel Articulate G1-P24-MS (K964603), determined to be substantially equivalent to a pre-enactment device on December 6, 1996. This device was marketed under the name inTune®
- The Philips XP Series (K921725), determined to be substantially equivalent to a pre-enactment device on August 11, 1992.
- Insound Medical Lyric, (K021867) determined to be substantially equivalent to K964603, K921725 and a pre-enactment device on November 19, 2002.

Device Description: The Lyric Hearing Aid 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 amplification characteristics are contained in digitally programmable memory and adjustment of device parameters is achieved through the proprietary HandFit™ Fitting System and Software.

Indications for Use: The Lyric 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 appropriately trained ENT Physician, Audiologist or Hearing Aid Dispenser and 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 Lyric Hearing Aid is an air-conduction programmable hearing aid with a deep canal fitting. The hearing aid's receiver is located 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 Lyric Hearing Aid is fit to the user with integrated soft retaining seals, like the Songbird Disposable Hearing Aid. Like both the Decibel and Songbird Hearing Aid, the size of the soft retaining seals is selected from a stock of available sizes. The custom battery of the Lyric Hearing Aid is discarded when the battery is depleted. Those characteristics are similar to the Songbird Disposable Hearing Aid.

Performance Data: The performance characteristics of the Lyric Hearing Aid have been evaluated in accordance with ANSI S3.22-2003, "Specification of Hearing Aid Characteristics." The devices met all applicable specifications developed by Insound Medical in accordance with design input specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 8 2008

InSound Medical, Inc.
c/o Ms. Susan Whichard, VP Marketing
39660 Eureka Drive
Newark, CA 94560

Re: K081136
Trade/Device Name: Lyric Hearing Aid
Regulation Number: 21 CFR 874.3300
Regulation Name: Hearing Aid
Regulatory Class: Class I (Exempt)
Product Code: ESD
Dated: April 10, 2008
Received: April 21, 2008

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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K081136

Indications for Use

510(k) Number: K081136

Device Name: Lyric

Indications For Use:

The 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 y an appropriately trained ENT Physician, Audiologist or Hearing Aid Dispenser and can remain the ear canal for up to 4 months or until the battery is depleted. Upon device removal the hearing aid is discarded.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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 Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K081136