3/19/99

K984547

RESOUND®
Hearing Health Care

EXHIBIT E

510(k) Summary of Safety and Effectiveness

[As required by 807.92(c)]

Submitter: ReSound Corporation
220 Saginaw Drive, Seaport Centre, Redwood City, CA 94063
Tel: 650 780-7800
Fax: 650 261-2284

Contact Person: Gary Roesel

Date: December 20, 1998

Common/Usual Name: Audiometer; Digital Master Hearing Aid

Proprietary Name: LGOB Test using ReSound® Digital 5000 Series Hearing Devices

Classification Panel 77, Procode ESD
CFR Part 874 – Ear, Nose, and Throat Devices
Subpart B – Diagnostic Devices - 874.1050 Audiometer
Subpart D – Prosthetic Devices - 874.3330 Master Hearing Aid

Establishment Registration: 2939186

References and Performance Standards:

Applicable sections of ANSI S3.6 - 1996, "Specification for Audiometers."

Applicable sections of ANSI S1.6-1984 (R 1990), "Preferred Frequencies, Frequency Levels and Band Numbers for Acoustical Measurements."

Applicable sections of ANSI S3.22-1996, "Specification of Hearing Aid Characteristics."

Software development and validation according to IEEE 1012-1986 and the FDA Guidelines for Computer Controlled Medical Devices.

J. B. Allen, J. L. Hall, and P. S. Jeng, "Loudness growth in ½-octave bands (LGOB) – A procedure for the assessment of loudness", Journal of the Acoustical Society of America - 1988 (2), 1990, pp. 745-753.

Substantial Equivalence: Using the Digital 5000 series of hearing devices to produce sound stimuli and perform LGOB loudness scaling measurements is substantially equivalent to other currently marketed audiometric diagnostic testing equipment, and is almost identical to that marketed as the ReSound® Portable Prescriptive Programming (P3) System (K912669).

Description: ReSound's Digital 5000 series hearing devices are built using a custom software programmable digital signal processor. The DSP includes two analog to digital converters (ADC) at the input stage and one digital to analog converter (DAC) at the output stage. Using a personal computer (PC) connected to the hearing device via standard CS45 cable, numerous signal processing and amplification parameters may be adjusted to help compensate for impaired hearing. In addition, proprietary software used only by hearing health care professionals can instruct the output DAC to produce specific sounds. These sound stimuli, when delivered at different amplitudes and frequencies, can be used for loudness scaling measurements helpful in fitting the hearing device more precisely to the patient's residual hearing dynamic range.

Intended Use: The "Loudness Growth in Octave Bands" (LGOB) loudness scaling test is intended to be used by hearing health care professionals as a supplemental audiometric measurement[1]. The LGOB test is intended to simplify and improve the accuracy of the fitting process for ReSound Digital or Analog hearing devices. Specifically, the test uses the Digital 5000 hearing device and proprietary software to directly produce ½ octave bands of noise presented at varying output levels and centered at varying frequencies. The hearing device wearer indicates their perceived loudness for each stimulus.

Predicate Device: The new Loudness Growth in Octave Bands (LGOB) test application of ReSound's Digital 5000 series hearing devices is substantially equivalent to the LGOB test developed by ReSound and provided with the original ReSound® P^3 System cleared under 510(k) K912669, September 16, 1991. In the predicate device, the LGOB sound stimulus was generated by the Personal Prescriptive Programmer hardware and delivered via a set of insert earphones.

The new LGOB application uses the patient's own digital hearing device or a stock "Digital Master" device to produce the sound stimulus

directly from the Digital to Analog converter within the hearing aid's Digital Signal [1]Processor. No insert earphones are required. Either BTE or Custom In The Ear devices can be used to perform the LGOB loudness scaling measurements. The test protocol is initiated and controlled by connecting a ReSound Corporation Digital hearing device to a personal computer and using proprietary fitting software (ReSound ReSource II). The patient's subjective loudness perception of each stimulus is recorded using the handheld Personal Selector, which is the identical recording device used with the original P^3 system. When the fitting computer system is disconnected, the hearing instrument functions normally.

Summary:

The ReSound® Loudness Growth in Octave Bands (LGOB) Loudness Scaling System is a new indication for use for the ReSound Digital 5000 hearing device family. Using the Digital 5000 series of hearing devices to perform LGOB measurements is substantially equivalent to the LGOB procedure pioneered by ReSound and marketed with the ReSound Portable Prescriptive Programming (P3) System (K912669). The software which controls the system is incorporated into ReSound® ReSource II software (K945750) that runs as a standalone application or can be integrated under the Noah operating system (K942749).

The LGOB test equipment is comprised of proprietary PC software and a ReSound Digital 5000 series hearing device. Similar to the Loudness Growth in Octave Bands (LGOB) test provided with the original ReSound® P^3 System, this new hearing device fitting method is designed to subjectively measure loudness growth in hearing-impaired subjects using the subject's own hearing aid, instead of using insert phones. The test is to be performed only by qualified hearing healthcare professionals. When the hearing aids are disconnected from the fitting computer, they function normally.

Substantial equivalence of this analysis system to currently marketed real ear systems mentioned above is based on the following:

(1) This system produces speech shaped noise stimuli delivered directly to the patient's ear canal;

(2) Measures the perceived intensity of the signals via a hand held 7-button Personal Selector, and;

(3) Displays the measurement results on the PC screen.

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[1] J. B. Allen, J. L. Hall, and P. S. Jeng, "Loudness growth in ½-octave bands (LGOB) – A procedure for the assessment of loudness", Journal of the Acoustical Society of America - 1988 (2), 1990, pp. 745-753.

The new LGOB test procedure requires the patient to evaluate ½ octave bands of pseudo-random noise signals generated directly by the Digital-to-Analog Converter (DAC) within the Digital hearing device. The patient indicates if they perceive the noise signal to be: Too Loud, Very Loud, Loud, Comfortable, Soft, Very Soft or Inaudible by entering their response with the hand held Personal Selector.

The proprietary software collects, labels and stores the resulting loudness sensitivity data. The fitting target and subsequent hearing aid amplification settings for the Digital 5000 (or other programmable ReSound hearing devices) are derived from the LGOB suprathreshold data and supplied audiometric threshold data. Any and all settings for the device which are chosen by the software can be easily and directly changed by the hearing device fitting professional, as with all other ReSound digital or analog hearing aids.

The new ReSound LGOB incorporates the patient's subjective response data along with the patient's audiometric data (entered separately) in the calculation of target response curves for the fitting of ReSound hearing devices. The intended use, method and theory of test operation, fundamental testing protocol, application and calibration of test results are equivalent to the predicate ReSound P system.

The use of the ReSound® LGOB loudness scaling system with the Digital 5000 series hearing devices does not significantly affect the safety or effectiveness of the currently marketed ReSound Digital 5000 family of hearing devices or the currently marketed ReSound ReSource II fitting software.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 19 1999

Gary W. Roesel
Director of Worldwide Technical Services,
Regulatory Affairs
ReSound Corporation
220 Saginaw Drive
Seaport Centre
Redwood City, CA

Re: K984547
LGOB Test using ReSound™ Digital 5000 Series
Hearing Devices
Dated: December 20, 1998
Received: December 22, 1998
Regulatory class: II
21 CFR 874.1050/Procode: 77 EWO
21 CFR 874.3330/Procode: 77 KHL

Dear Mr. Roesel:

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

RESOUND
Hearing Health Care

510(k) Premarket Notification – LGOB Using Digital Hearing Devices

EXHIBIT B

INDICATION FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: ReSound LGOB Procedure using Digital 5000 series hearing devices

Indications for Use:

The ReSound® Loudness Growth in Octave Bands (LGOB) Loudness Scaling System is a new indication for use for the ReSound Digital 5000 hearing device family. The control for the system is incorporated into ReSound ReSource II fitting application software. The testing procedure is intended to be performed only by qualified hearing healthcare professionals.

The purpose of the ReSound LGOB test is to evaluate a patient's suprathreshold hearing at specific frequencies. This is the range of hearing above a person's threshold level but below their uncomfortable loudness level. The results of this test are used by the ReSource software to calculate hearing instrument fittings that are better tailored to the patient's residual dynamic range of hearing. The LGOB test procedure requires the patient to evaluate narrow bands of noise signals generated directly the Digital-to-Analog converter within the hearing device. The patient indicates if the noise signal is Too Loud, Very Loud, Loud, Comfortable, Soft, Very Soft or Inaudible by entering their response with the hand held Personal Selector, which is the identical recording device used with the original P^3 system from ReSound.

The new LGOB application uses the patient's own digital hearing device or a stock "Digital Master" device to produce the sound stimulus directly from the Digital to Analog converter (DAC) within the hearing aid's Digital Signal Processor. No insert earphones are required. Either BTE or Custom In-The-Ear devices can be used to perform the LGOB loudness scaling measurements. The test protocol is initiated and controlled by connecting a Digital hearing device to a personal computer and using proprietary fitting software (ReSource II). When the fitting computer is disconnected, the hearing instrument functions normally.

Results from the test are used to provide fitting recommendations and initial device amplification parameter settings for the Digital 5000 and other programmable ReSound hearing devices.

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K984547