K960229

RESOUND®
HEARING HEALTH CARE

MAR - 7 1996

510(k) Premarket Notification - Real Ear Loudness Mapping (RELM)

EXHIBIT E

Summary of Safety and Effectiveness

The ReSound® Real Ear Loudness Mapping (RELM) System is substantially equivalent to currently marketed audiometric diagnostic testing equipment and hearing aid analysis systems such as: the ReSound® Portable Prescriptive Programming (P^3) System[1] and the Frye Electronics, Inc., Type 6400 Real Ear Hearing Aid Analyzer[2]. The software for the system is substantially equivalent to the ReSound® ReSource™ software[3] that runs under the Noah[4] operating system.

The RELM test equipment is comprised of proprietary PC software, a sound field speaker system, and a real ear probe microphone. Similar to the Loudness Growth in Octave Bands (LGOB) Test provided with the ReSound® P^3 System, this new hearing device fitting method is designed to measure loudness growth in hearing-impaired subjects in ***sound field***, instead of with insert phones, in the unaided ***and aided*** conditions, through the use of subjective ***and objective*** measures, thus integrating both electroacoustic and psychoacoustic test capabilities.

Substantial equivalence of this analysis system to currently marketed real ear systems as mentioned above is based on the following: (1) this system produces computer generated stimuli delivered via speakers; (2) measures the intensity of the signals via a probe microphone in the patient's ear canal, and; (3) displays the values in the form of frequency intensity curves on the PC screen. The RELM system goes one step further from a real ear analysis system by incorporating the patient subjective response data in the calculation of target response curves for determining the hearing device fitting parameters. This aspect of the system is substantially equivalent to the functions of the ReSound® P^3 System that calculates hearing device fitting parameters by incorporating LGOB patient test data with the patient's audiometric data and programs the hearing device. As the RELM System monitors the aided sound pressure levels in the ear canal via the probe microphone, the hearing device fitting parameters may be "fine-tuned" to the patient's loudness target response.

The use of the ReSound® RELM System does not significantly affect the safety or effectiveness of the currently marketed ReSound® Personal Hearing Systems.

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[1] ReSound® Portable Prescriptive Programming (P^3) System, 510(k) No. K912669, September 16, 1991
[2] Frye Electronics, Inc., Type 6400 Real Ear Hearing Aid Analyzer, 510(k) No. K872242, July 10, 1987
[3] ReSound® ReSource™, 510(k) No. K945750, March 7, 1995
[4] HI-Pro/Noah, 510(k) No. K942749, July 18, 1994