Decibel

K964603

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SECTION 2

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: Decibel Instruments, Inc.
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Contact Person: Adnan Shennib, President

Date of Summary: November 18, 1996

Device Name: Articulate™ G1 Series Hearing Aids

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

- The Starkey Laboratories Tympanette (K933407), determined to be substantially equivalent to a pre-enactment device on October 7, 1993;
- The General Hearing Instruments In-the-Ear Hearing Aid (K850123), determined to be substantially equivalent to a pre-enactment device on March 21, 1985; and
- The Resound Corporation Resound ITE Hearing Enhancement System (HES) (K884871), determined to be substantially equivalent to a pre-enactment device on February 21; 1989.

Device Description: The Articulate G1 Series Hearing Aids amplify and deliver sounds via air conduction to the external ear of persons with hearing losses. The microphone transforms sound waves into electrical signals and delivers it to the hearing aid circuit, which is powered by the battery. In the non-programmable Articulate models, the potentiometers of the circuit are used by the hearing aid dispenser to manually modify the amplification characteristics of the incoming signal. In the programmable Articulate models, the amplification characteristics are contained in digitally programmable memory; the programming port allows direct programming of the circuit and adjustment of device parameters through the interface to a personal computer and proprietary Articulate Programming Software.

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Intended Use: The Articulate G1 Series Hearing Aids are wearable, sound-amplifying devices that are intended to compensate for impaired hearing. The intended use of the Articulate series hearing aids is identical to that of the legally marketed predicate devices.

Descriptive Summary Of Technological Characteristics And Those Of Predicate Devices:
The non-programmable Articulate G1 Series models (G1-12-MM, G1-12-MS, G1-24-MM, and G1-24-MS) are air conduction hearing aids, with in-the-canal to deep canal fitting. Electronics are external to the second bend of the ear canal, with receiver located around the second bend, transmitting sound to the tympanic membrane. The potentiometers of the circuit are used to change the amplification characteristics of the incoming signal. Two volume control settings are modified by a switch on the faceplate. These characteristics are similar to the Starkey Laboratories Tympanette and to the General Hearing Instruments In-the-Ear Hearing Aid (EZ-Ear).

The programmable Articulate G1 Series models (G1-P24-MM, and G1-P24-MS) are air conduction hearing aids, with in-the-canal to deep canal fitting. Electronics are external to the second bend of the ear canal, with receiver located around the second bend, transmitting sound to the tympanic membrane. Amplification characteristics are contained in digitally programmable memory and direct programming of hearing aid circuit occurs through interface to a personal computer and and programming software. Two volume control settings are modified by a switch on the faceplate. These characteristics are similar to the General Hearing Instruments In-the-Ear Hearing Aid (EZ-Ear) and to the Resound ITE Hearing Enhancement System (HES).

Performance data: The performance characteristics of the Articulate G1 Series Hearing Aids 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 specification.

Lisa S. Jones

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Nov. 15, 1996
Date