K972998

A SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

Name of Device: Siemens PRISMA Behind the Ear and Custom Hearing Instruments SEP - 5 1997

Type of Device: Behind the Ear and Custom Hearing aid substantially equivalent to other Behind the Ear (BTE) and Custom hearing aids (In The Ear, In The Canal, Half Shell, Mini-Canal, Completely In the Canal) on the market.

Intended Use: To amplify and transmit sound to the ear.

Features: PRISMA Behind the Ear and Custom Hearing Instruments are digitally programmable instruments. The dispenser programs the instrument using Siemens PC CONNEXX software with HiPro ™ hardware (K942749), Siemens Personal Programmer 2000, or UNITY with HiPro hardware This device is intended to compensate for a wide range of moderate to severe hearing losses including flat, ski-slope and reverse slope losses. It features digital control of a highly flexible digital signal processor

Up to 32 digitally adjustable parameters and two listening situations (memories) are accessible to shape and modify the instrument's response, depending on the model configuration. These include: Channel Delineation, Curvilinear Compression, Linear Compression, Syllabic Compression, Dual Compression, Voice Activity Detection System, Channel Gain, Cross Channel Shaping, Interchannel coupling, Twin Microphone System/Direction Mic, Low level Squelch, Second Program.

Assembly: Assembled from standard components that are widely utilized by other hearing aid manufacturers.

Technical Characteristics: Technical specifications comply with s3.22-1987 ANSI Specifications

Fit: The frequency response of the product is dictated by the individual Audiogram from each client and the settings of the programmable controls.

Controls: User adjustable controls may be found on the Behind-the-Ear model which include a Microphone-Telecoil-Off (M-T-O) switch, and a momentary push-button switch to change between the two stored memories. Depending on the specific configuration of the instrument as ordered by the hearing instrument professional, some of these user controls may not be present. With the custom products, PRISMA comes standard with no user adjustable controls unless specifically requested by the hearing instrument professional, in which case a push button switch and/or directional microphone is available.

Power: Standard Hearing Aid Batteries: 5A,10A, 13, 312 and 675

A User's manual and General Information for Hearing Aid Users Guide is supplied with each hearing aid.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 5 1997

Robert H. Bea
Director of Quality Assurance & Regulatory Affairs
Siemens Hearing Instrument, Inc.
10 Constitution Avenue
P.O. Box 1397
Piscataway, New Jersey 08855-1397

Re: K972998
PRISMA Digital Hearing Aid
Dated: August 8, 1997
Received: August 12, 1997
Regulatory class: I
21 CFR 874.3300/Procode: 77 ESD

Dear Mr. Bea:

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 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 requirement, 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.

While your device has been deemed substantially equivalent to other legally marketed hearing aids, please be advised that electromagnetic interference from digital cellular telephones, as well as from other sources is increasingly becoming a concern. Typically, this interference takes the form of a buzzing sound that can range from annoying to very loud and may render a hearing aid temporarily ineffective for the wearer. Because electromagnetic interference may affect your device, you may be asked to test for electromagnetic compatibility in the future. In this interim period, we encourage you to modify your device labeling to inform practitioners and users of the potential for electromagnetic interference. Please be aware that a 510(k) submission is required for any claims that infer that your device is compatible with potential sources of electromagnetic interference, such as "compatible with digital cellular telephones", and that data supporting such claims is necessary.

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/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEVICE INDICATION FOR USE

Device Name: Classification Name: Air Conduction Hearing Aid
Common/Usual Name: Behind the Ear, In the Ear, Half Shell, In the Canal, Mini-Canal and Completely in the Canal Hearing Aid.

Registration No.: Establishment Registration Number: 2217809

Indication for Use: A wearable sound-amplifying device that is intended to help cmpensate for impaired hearing. Sounds are electronically amplified and transmitted to the ear.

I certify that, in my capacity as Director of Quality Assurance & Regulatory Affairs of Siemens Hearing Insatruments, Inc., I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

Signature

Robert H. Bea, Director of Quality Assurance & Regulatory Affairs

August 18, 1997

Date

Restricted Device
Per 874.420 and 421

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K972998

* Must be signed by a responsible person of the firm required to submit the premarket notification (e.g., not a consultant for the 510(k) submitter.)