K073384

510(k) Summary (per 21 CFR 807.92)

Submitter:
Intelligent Hearing Systems
6860 SW 81st Street
Miami, FL 33143

Contact :
Edward Miskiel, Ph.D.
Telephone: (305) 668-6102
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Date Summary Prepared: November 29, 2007

Device Identification:
Common Name: Acoustic Coupler
Proprietary Name: Smart Coupler

Predicate Device: VIASYS Healthcare Comfort Cup & Ear Tip Accessories (K031713)

Device Description: The Smart Coupler is a non-invasive, cutaneous, passive, sound-delivery device accessory that provides a coupling interface between the patient's ear and the auditory stimulator used during audiometric testing. The device is a biocompatible, non-sterile, single patient use, disposable device.

The anatomical sites of contact for the Smart Coupler are the external skin surrounding the ear (circumaural model), the external skin of the outer ear (supra-aural model), or the external skin of the ear canal (intra-aural model) with the contact object being a thin layer of medical-grade, biocompatible adhesive hydrogel, used for adhering the Smart Coupler device to the patient.

Intended Use: The Smart Coupler is intended for short-term, non-invasive use to support auditory evaluation studies (including use with audiometers, auditory evoked potential and otoacoustic emissions devices) on patients of all ages. This is the same intended use as that of the predicate device.

Comparison Summary of Technological Characteristics:

Parameter for Comparison	Predicate Device	Similarity or Difference to Predicate Device
Target Population	Newborns and all ages (assumed).	Same.
Where Used	Clinical setting.	Same.
Anatomical Sites	Head and external ear.	Same.
Sterility	Not supplied sterile.	Same.

Parameter for Comparison	Predicate Device	Similarity or Difference to Predicate Device
Biocompatibility	Unknown.	All material in contact with the patient successfully passed the biocompatibility testing criteria specified in the ISO 10993 standard for short-term skin contact (cytotoxicity, skin irritation, & skin sensitization).
Design	2 models available: • Circumaural • Intra-aural	3 models available: • Circumaural • Intra-aural • Supra-aural
Materials	Foam, flexible elastomeric material, and adhesive material to adhere to skin surface.	Same (expect no foam).
Human Factors	Simple, easy-to-follow instructions.	Same.
Standards	None known.	Same.
Energy Used and/or Delivered	Device is passive and does not consume or produce any energy. Only acoustic energy from a different source is conveyed.	Same.
Chemical Safety	No chemicals are involved in the use of this device.	Same.
Mechanical Safety	No mechanical parts.	Same.
Electrical Safety	Device is not electrical in nature.	Same.
Thermal Safety	Device is not thermal in nature.	Same.

Substantial Equivalence:
This submission includes the results of performance testing of prototype devices to specifications. The results were as expected and no new issues of safety and effectiveness were raised as a result of the testing.

Conclusions:
Based on the information presented in this submission, the Smart Coupler device is as safe and effective as and is substantially equivalent to the identified predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 28 2008

Intelligent Hearing Systems
c/o Edward Miskiel, Ph.D.
6860 S.W. 81st Street
Miami, FL 33143

Re: K073384
Trade/Device Name: Smart Coupler
Regulation Number: 21 CFR 882.1900
Regulation Name: Evoked Response Auditory Stimulator
Regulatory Class: Class II
Product Code: GWJ
Dated: February 14, 2008
Received: February 15, 2008

Dear Dr. Miskiel:

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

K073384

Indications for Use

510(k) Number (if known): K073384

Device Name: Smart Coupler

The Smart Coupler is a passive, ear-coupling, sound-delivery device accessory intended for short-term, non-invasive use to support auditory evaluation studies (including use with audiometers, auditory evoked potential and otoacoustic emissions devices) on patients of all ages. The Smart Coupler is a biocompatible, non-sterile, single patient use, disposable device.

The Smart Coupler is intended to be used by trained personnel in a hospital, nursery, clinic, audiologist's, or physician's office or other appropriate setting.

The anatomical sites of contact for the Smart Coupler are the external skin surrounding the ear (circumaural model), the external skin of the outer ear (supra-aural model), or the external skin of the ear canal (intra-aural model) with the contact object being a thin layer of medical-grade, biocompatible adhesive hydrogel, used for adhering the Smart Coupler device to the patient.

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)

Daniel C Clapper

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

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