



K090579

510(k) Summary

JUL - 7 2009

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

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Contact Person: Edward Miskiel, Ph.D.

Date Summary Prepared: June 18, 2009

Trade Name: SmartScreener-Plus2

Common Name(s): Auditory Evoked Potential Device, Otoacoustic Emissions Device, Automated Hearing Screener.

Classification Name: Auditory Evoked Response Stimulator (per CFR 882.1900) & Audiometer (per CFR 874.1050)

Predicate Device(s): Bio-logic ABaer Cub with integrated OAE and ABR functions
510(k) #K021801
Intelligent Hearing Systems SmartEP-ASSR 510(k) #K031051

Description of the Device:

The SmartScreener-Plus2 is a noninvasive device used to test for hearing and related neurological abnormalities. The device is especially indicated for use in the screening of infants to determine hearing loss.

The SmartScreener-Plus2 device records and detects auditory evoked potentials (AEPs) and otoacoustic emissions (OAEs) which are generated in response to a series of auditory stimuli delivered to the patient. AEPs are electrical signals produced by the patient's neurological activity and are picked up by electrodes attached to the patient's skin. The portion of the AEP that originates from the anatomical structures of the inner ear to the auditory brainstem is commonly called the Auditory Brainstem Response (ABR). Otoacoustic emissions are acoustic signals produced by the patient's inner ear and are picked up by a sensitive microphone located in an OAE probe. The SmartScreener-Plus2 device is capable of recording Transient Evoked OAEs (TEOAEs or TrOAEs), and Distortion Product OAEs (DPOAEs)

The SmartScreener-Plus2 uses advanced signal processing technology to separate AEPs and OAEs from background noise and other physiological activity. The device uses proven statistical algorithms to automatically determine if there is an AEP or OAE response present to the auditory stimuli delivered to the patient. A user, with device administrator approved password security clearance, is able to set the output level of the stimulus. AEP stimulus levels

between 30 to 40 dB nHL, and TEOAE stimulus level of 85 dB SPL, and DPOAE stimulus levels of 65 and 55 dB SPL are commonly used for newborn hearing screening applications.

The SmartScreen-Plus2 device is simple to operate. It does not require any special technical skills or interpretation of results. Basic training is sufficient to learn how to use the device.

Indications for Use:

The SmartScreener-Plus2 device is indicated for use in the recording and automated analysis of human physiological data necessary (auditory brainstem responses and/or otoacoustic emissions) for the diagnosis of auditory and hearing-related disorders. The device is especially indicated for use in the screening of infants to determine hearing loss.

Sites appropriate for use include the well-baby nursery, neonatal intensive care unit (NICU), mother's bedside, outpatient clinic, audiologist's office, or doctor's office. The device is simple to operate. It does not require special technical skills or interpretation of results by the device operator. Basic training with the device is sufficient to learn how to operate it.

The SmartScreener-Plus2 device can be used for patients of all ages, from children to adults, including infants and geriatric patients. It is especially indicated for use in testing individuals for whom behavioral audiometric results are deemed unreliable, such as infants, young children, and cognitively impaired or uncooperative adults.

The possible anatomical sites of contact are the patient's ear, ear canal, and/or external skin surrounding the ear (with the contact object being a sound delivery eartip, headphone cushion, or an acoustic ear coupler such as a circumaural ear cup, intra-aural ear bud, or supra-aural ear patch), the patient's head (with the contact object being a bone vibrator), and the patient's head, nape of the neck and shoulder (with the contact object being electrodes that are capable of measuring bio-potentials).

The SmartScreener-Plus2 device is for prescription use.

Comparison with Predicate Device:

Comparisons of technological characteristics of the SmartScreener-Plus2 with the predicate devices (Bio-logic ABAer Cub with integrated OAE and ABR functions and the Intelligent Hearing Systems SmartEP-ASSR) are given in the table below:

Parameter for Comparison	Predicate Device Bio-logic ABAer Cub with integrated OAE and ABR functions (K021801)	Predicate Device IHS SmartEP-ASSR (K031051)	Similarity or Difference to Predicate Devices
Target Population	Patients of all ages.	Same.	Same.
Where Used	Clinical setting.	Same.	Same.
Anatomical Sites	Scalp, ear and other skin sites.	Same.	Same.
Sterility	None required.	Same.	Same.
Biocompatibility	Completely biocompatible.	Same.	Same.

Design	Main hardware unit (housing circuitry, supplies, and equipment) connected to (1) patient cables and transducers and (2) a portable computer (with installed testing software).	Same.	Same.
Components/ Materials	Main hardware unit, transducers, acoustic couplers, electrodes, cables, computer, printer and cart.	Same.	Same.
Human Factors	Simple, easy-to-follow instructions and software user interface.	Same.	Same.
Standards	None known.	Same.	Same.
Energy Used and/or Delivered	Stimulation of auditory system.	Same.	Same.
Chemical Safety	No chemicals are involved in the use of this device.	Same.	Same.
Mechanical Safety	No mechanical parts in contact with patient.	Same.	Same.
Electrical Safety	Meets IEC60601-1, UL2601-1, CSA-C22.2 No. 601.1, AAMIES1, and CE Mark.	Meets EN60601-1, EN60601-1-2, EN60601-2-40, EN55011, EN61000-3-2, EN61000-3-3, and CE Mark.	Same as SmartEP-ASSR (K031051).
Thermal Safety	Device is not thermal in nature.	Same.	Same.

Substantial Equivalence:

Based on the information presented here, the SmartScreener-Plus2 device is substantially equivalent to the Bio-logic ABAer Cub with Integrated OAE and ABR and the Intelligent Hearing Systems SmartEP-ASSR devices.

Performance Testing:

This submission includes a comparison table of specifications for both the SmartScreener-Plus2 device and the predicate devices. The SmartScreener-Plus2 device specifications were verified and validated.

Conclusions:

Based on the information presented in this submission, the SmartScreener-Plus2 device is as safe and effective as the identified predicate devices, the Bio-logic ABAer Cub with integrated OAE and ABR and the Intelligent Hearing Systems SmartEP-ASSR.



Food and Drug Administration
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Rockville MD 20850

Intelligent Hearing Systems
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Re: K090579
Trade/Device Name: SmartScreener-Plus2
Regulation Number: 21 CFR 882.1900
Regulation Name: Auditory Evoked Response Stimulator
Regulatory Class: Class II
Product Code: GWJ, EWO
Dated: June 18, 2009
Received: June 24, 2009

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

A handwritten signature in black ink, appearing to read "Malvina B. Eydelman, M.D.", with a stylized flourish at the end.

Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic, Neurological
and Ear, Nose and Throat Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K090579

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The SmartScreener-Plus2 device is for prescription use.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of ~~CDRH~~ Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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