K061443

INTELLIGENT HEARING SYSTEMS

JUN 2 3 2006

Special 510(k) Summary

Prepared By: Intelligent Hearing Systems
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Date Summary prepared: May 23, 2006

Name of the Device: **Smart USB*Lite*** (with options of SmartEP, SmartScreener, SmartOAE, SmartTrOAE, and SmartEP-ASSR)

Common Name: Auditory Evoked Potential System & Otoacoustic Device

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

Predicate Device(s): SmartEP (K904926), SmartScreener (K925648), SmartOAE (K964426), SmartTrOAE (K023859), SmartEP-ASSR (K031051), and Opti-Amp DC-Powered (K052060).

Device Description: Smart USB*Lite* is an auditory evoked potential and otoacoustic emission system that is capable of recording and measuring auditory evoked potential, otoacoustic emission, and auditory steady-state evoked potential data.

The Smart USB*Lite* system combines the following FDA 510(k) previously cleared devices into a repackaged, smaller-sized, single integrated unit: SmartEP (K904926), SmartScreener (K925648), SmartOAE (K964426), SmartTrOAE (K023859), SmartEP-ASSR (K031051), and Opti-Amp DC-Powered (K052060).

Intended Use: The Smart USB*Lite* device is intended to be used as a diagnostic aid in auditory and hearing related disorders, as an objective measure of cochlear function, and as an adjunctive tool in the estimation of behavioral hearing thresholds on patients of all ages. This is the **same intended** use as that of the predicate devices.

Technological Characteristics:

The Intelligent Hearing Systems (IHS) family of products is intended to be used for recording and analysis of human physiological data for the purpose of neurological diagnosis, screening, and treatment of sensory disorders. The Smart USB*Lite* device referenced above is the latest in a series of systems of this type marketed by IHS. Other related devices comprising the IHS family of products include:

1) 510(k) #K904926 – SmartEP Auditory Evoked Potential System
2) 510(k) #K904926 – SmartScreener Automated Auditory Evoked Potential Screening System
3) 510(k) #K964426 – SmartOAE Distortion-Product Otoacoustic Emissions System
4) 510(k) #K023859 – SmartTrOAE Transient Otoacoustic Emissions System
5) 510(k) #K031051 – SmartEP-ASSR Auditory Steady-State Response System
6) 510(k) #K052060 – Opti-Amp DC-Powered Physiological Signal Amplifier System

The feature modifications described in this Special 510(k) are to incorporate a repackaged variation of the listed predicate devices combined into a smaller-sized single integrated unit, the Smart USB*Lite*. The Smart USB*Lite* device is identical to the predicate device(s) in its intended use and methodologies, which have not changed as a result of modifications to the general specifications of the device. The Smart USB*Lite* device can be used to perform all four different kinds of tests provided by the listed predicate devices, namely: auditory evoked potentials (AEP), auditory evoked potential screening, distortion-product otoacoustic emissions (DPOAE), transient otoacoustic emissions (TrOAE), and auditory steady-state response (ASSR) testing.

The modifications associated with this new Smart USB*Lite* device are mostly to the physical layout and aesthetics of the device hardware only, and do not change the software in any significant way. The new device utilizes hardware variations primarily to enhance size-reduction and portability, while still performing the same hardware functions in essentially the same ways as the predicate devices. The Smart USB*Lite* uses the same five software packages used by the five individual predicate devices (i.e., SmartEP, SmartScreener, SmartOAE, SmartTrOAE, and SmartEP-ASSR software). The software has remained essentially the same for the new device, with small variations to accommodate differences in hardware. The same functionality and user interfaces have remained. Together, these minor hardware and software changes implement the same functionality and perform the same intended uses as the predicate devices in a single integrated unit.

The Smart USB*Lite* hardware is very similar in electronics design to the predicate device hardware, except that the electronics hardware has been repackaged into a single, smaller, stand-alone box. Unlike the predicate devices, there is no separate pre-amplifier unit connected to the patient in the Smart USB*Lite* system. Instead, all of the pre-amplifier electronics have been embedded inside of the SmartUSB*Lite* receiver unit. The same patient isolation methods are used.

Besides packaging, the other minor modifications to the Smart USB*Lite* over the previous devices are the number of input/output channels, gain, and filter specifications/characteristics. A complete comparison between the Smart USB*Lite* and the predicate devices is given in specifications Table 1.

Figures 1-2 give simplified block diagrams for the predicate devices system hardware and the new Smart USB*Lite* system.

Safety and Effectiveness:

The Smart USB*Lite* utilizes many of the same design principles, circuit designs, and operating principles as are used in the predicate devices. All of the modifications of the Smart USB*Lite* device were designed in accordance with procedures that meet FDA QSR Design Control and ISO-13485:2003 specifications.

The Smart USB*Lite* device will be evaluated and certified for both electromagnetic compatibility and electrical safety prior to release, by a certified National Recognized Test Laboratory (NRTL),

Washington Laboratories, Ltd.
7560 Lindbergh Dr.
Gaithersburg, Maryland 20879,

which will conduct the appropriate EMI/EMC testing for medical electrical equipment, to elements of the requirements of:

- EN60601-1:1990: "*Medical Electrical Equipment, Part 1: General Requirements for Safety.*"
- EN60601-1-2:2001: *"Medical Electrical Equipment, Part 1: General Requirements for Safety.2.Collateral Standard: Electromagnetic Compatibility – Requirements and Tests"*
- EN55011:1998: *"Industrial, Scientific, & Medical (ISM) Radio-Frequency Equipment – Radio Disturbances Characteristics – Limits & Methods of Measurements"*
- EN61000-3-2:1995: *"Electromagnetic Compatibility (EMC) – Part 3-2:Limits for Harmonic Current Emissions"*
- EN61000-3-3:1995: *"Electromagnetic Compatibility (EMC) Part 3-3: Limits of Voltage Fluctuations and Flicker in Low-Voltage Supply Systems for Equipment with Rated Current up to 16 A"*

Substantial Equivalence Based on Assessment of Performance Data:

The Smart USB*Lite* is substantially equivalent to the predicate SmartEP, SmartScreener, SmartOAE, SmartTrOAE, SmartEP-ASSR, and Opti-Amp DC-Powered devices marketed by Intelligent Hearing Systems with FDA 510(k) clearance numbers K904926, K925648, K964426, K023859, K031051, and K052060 (respectively). The intended use of the device has not changed as a result of modifications to the general or electrical specifications of the device(s) listed below.

SPECIFICATIONS

Parameter	Predicate Devices **SmartEP (K904926)** **SmartScreener (K925648)** **SmartOAE (K964426)** **SmartTrOAE (K023859)** **SmartEP-ASSR (K031051)** **Opti-Amp DC Powered (K052060)**	**Device Under Current 510(k) Review** **Smart USB*Lite***
Intended Use	SmartEP: Stimulate, record, & process auditory evoked potentials SmartScreener: Stimulate, record, & process auditory evoked potentials using simplified user interface, with automated evoked response detection SmartOAE: Elicitation and measurement of distortion product otoacoustic emissions SmartTrOAE: Elicitation and measurement of transient and spontaneous otoacoustic emissions SmartEP-ASSR: Stimulate, record, & process auditory steady-state evoked potentials.	Same
Indications for Use	SmartEP, SmartScreener, & SmartEP-ASSR: The recording & analysis of physiological data necessary for the diagnosis of auditory and hearing-related disorders. SmartOAE & SmartTrOAE: Determination of cochlear function in patients of all ages.	Same
Target Population	All Ages	Same
Design	External box housing circuitry connected to personal computer via a USB connection	Same

Materials	Assorted electrical components, circuit boards, sound transducers, microphone, electrodes, and disposable probe ear tips	Same
Sterility	None required	Same
Biocompatibility	Completely Biocompatible	Same
Anatomical Site	Ear canal, arms, and head	Same
Energy Delivery	Stimulation of the ear with sound signals	Same
Where Used	Clinical Setting	Same
Safety	Meets EN 60601-1	Same
General		
Operating Temperature	15°C to 40°C	Same
Storage Temperature	5°C to 50°C	Same
Relative Humidity	15% to 90% (at 40°C Non-Condensing)	Same
Atmospheric Pressure	None Specified	Same
Mode of Operation	Continuous	Same
Type of Protection	Class I (IEC 601)	Same
Degree of Protection	Type B (IEC 601)	Same
Protection Against Fluids	IPX0 – Ordinary Equipment (IEC 601)	Same
Degree of Mobility	Portable Equipment	Same
Vibration and Shock	N/A	Same
Expected Lifetime	10 Years from date of manufacture	Same
Electrical Specifications		
Power Supply	<u>Predicate Hardware Version # 1:</u> External medical grade power supply 3 Outputs: +15V (2.5A), -15V (0.5A), and +5V (5A) OR <u>Predicate Hardware Version # 2:</u> Internal medical grade power supply 3 Outputs: +15V (2A), -15V (0.7A) and +5V (5A)	External medical grade power supply 1 Output: +5V (2A)

Rated Input Current	Predicate Hardware Version # 1: 1.3 Amps OR Predicate Hardware Version # 2: 2.0 Amps	0.5 Amps
Rated Frequency	50-60 Hz	Same
Rated Input Voltage	100-240 VoltsAC	Same
Rated Max Input Power	40 Watts	10 Watts
Fuse Type	Predicate Hardware Version # 1: N/A (External Power Supply) OR Predicate Hardware Version # 2: Time Lag Fuse (IEC 60127-2 compliant)	N/A (External Power Supply)
Fuse Rating	Predicate Hardware Version # 1: N/A (External Power Supply) OR Predicate Hardware Version # 2: 1.6 Amps, 250 VoltsAC	N/A (External Power Supply)
Patient Isolation	4000Vdc, 10 Mega Ohms	Same
Data Acquisition		
A/D Resolution	16 bit	Same
Artifact Rejection	Programmable	Same
Input Channels	SmartEP, SmartScreener, SmartEP-ASSR: 1-4 Channels (Optically Isolated) SmartOAE, SmartTrOAE: 1-2 Channels	Smart USB*Lite* (EP, Screener, ASSR): 1 Channel (Optically Isolated) Smart USB*Lite* (DPOAE, TrOAE): 1 Channel (Optically Isolated)
Amplifiers/Filters		
Gain	SmartEP, SmartScreener, SmartEP-ASSR: Variable (30k-300k) SmartOAE: Fixed (100) SmartTrOAE: Variable (100-10k)	Smart USB*Lite* (EP, Screener, ASSR): Fixed (100k) Smart USB*Lite* (DPOAE): Same Smart USB*Lite* (TrOAE): Same

Lowpass Filter	SmartEP, SmartScreener: Variable (30-5000 Hz) SmartOAE: 100 kHz SmartTrOAE: 5000 Hz SmartEP-ASSR: Variable (30-5000 Hz)	Smart USB*Lite* (EP, Screener): Fixed (1500 Hz) Smart USB*Lite* (DPOAE): Same Smart USB*Lite* (TrOAE): Same Smart USB*Lite* (ASSR): Fixed (300 Hz)
Highpass Filter	SmartEP, SmartScreener, SmartEP-ASSR: Variable (1- 500 Hz) SmartOAE: 200 Hz SmartTrOAE: 450 Hz	Smart USB*Lite* (EP, Screener, ASSR): Fixed (30 Hz) Smart USB*Lite* (DPOAE): Same Smart USB*Lite* (TrOAE): Same
Filter Slope	SmartEP, SmartScreener, SmartEP-ASSR: 6 dB/octave SmartTrOAE: 24 dB/octave	Smart USB*Lite* (EP, Screener, ASSR): 12 dB/octave Smart USB*Lite* (TrOAE): Same
Notch Filter	50/60Hz	Same
Noise Level	SmartEP, SmartScreener, SmartEP-ASSR: 0.33 µV RMS (1-3000 Hz) 0.12 µVpp for 1024 averaged sweeps SmartOAE, SmartTrOAE: 40 µV RMS	Smart USB*Lite* (EP, Screener, ASSR): 0.13 µV RMS (30-1500 Hz) 0.1 µVpp for 1024 averaged sweeps Smart USB*Lite* (DPOAE, TrOAE): Same
Input Impedance	Opti-Amp DC Powered: 5 MegaOhms	Same
CMR Ratio	Opti-Amp DC Powered: 117 dB at 60Hz, 110 dB at 1kHz	Same

Auditory Stimuli		
Types	SmartEP, SmartScreener, SmartEP-ASSR: Clicks, Pure Tones, Multifrequency Stimuli SmartOAE: Multifrequency Tones SmartTrOAE: Clicks, Tone Bursts	Same
Duration	SmartEP, SmartScreener, SmartEP-ASSR, SmartTrOAE: 25-5000 µsec SmartOAE: Continuous	Same
Envelopes	Linear, Blackman, Gaussian, Hanning, Rectangular, Triangular, Trapezoidal, Exact Blackman, Cosine, Cosine Squared, Cosine Cubed	Same
Intensity	SmartEP, SmartScreener: 0-125 dB SPL SmartOAE: 55-80 dB SPL SmartTrOAE: 60-90 dB SPL SmartEP-ASSR: 0-80 dB SPL	Same
Repetition Rate	SmartEP, SmartScreener, SmartEP-ASSR: 1-100 Hz SmartOAE: Continuous SmartTrOAE: 1-50 Hz	Same
Test Frequencies	500-16,000 Hz	Same
Presentation	SmartEP, SmartScreener, SmartEP-ASSR: Monaural or Binaural SmartOAE, SmartTrOAE: Monaural	Same

Masking	White Noise Programmable	Same
Transducers	Insert Earphones, Bone Vibrator, Headphones, Sound Field, Ear Probe	Insert Earphones, Headphones, Ear Probe
Analysis & Measurement Parameters		
Analysis Window	SmartEP, SmartEP-ASSR: Variable (up to 2.5 msec) SmartScreener: Fixed (25.6 msec) SmartOAE: Fixed (102.4 msec) SmartTrOAE: Fixed (2.5-22.5 msec post-stimulus)	Same
Artifact Rejection Threshold	SmartEP, SmartScreener, SmartEP-ASSR, SmartTrOAE: User Selectable SmartOAE: Automated/Fixed	Same
Measured Values	Response Level (dB SPL) Noise Level (dB SPL) Signal to Noise Ratio (dB SPL) Response Latency (msec) Frequency (Hz)	Same
Computer Requirements		
Computer Type	Personal Computer	Same
Operating System	Microsoft Windows 2000 or XP	Same
Interface Connection	USB (Universal Serial Bus)	Same

Table 1: General, electrical, and performance specifications of predicate devices & current device under Special 510(k) review.

Predicate Device Hardware Block Diagram

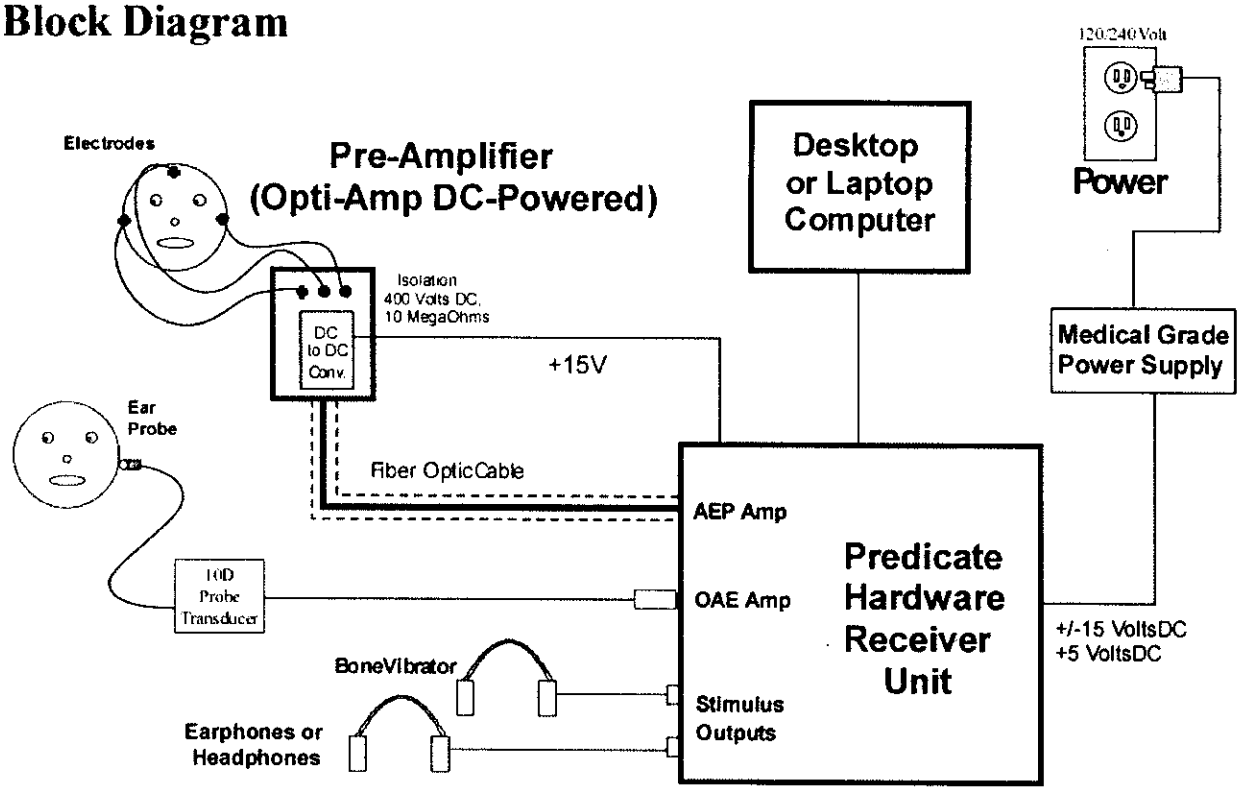

Figure 1: Block diagram of the predicate devices hardware system. This system uses an Opti-Amp pre-amplifier unit (refer to FDA 510(k) numbers K914876 and K052060) connected to the patient, which is powered by one of two schemes: 1) Two AA batteries housed internally (K914876), or 2) +15Volts taken from the hardware receiver unit and regulated using a high voltage isolation DC-DC converter (K052060).

Smart USB*Lite* Hardware Block Diagram

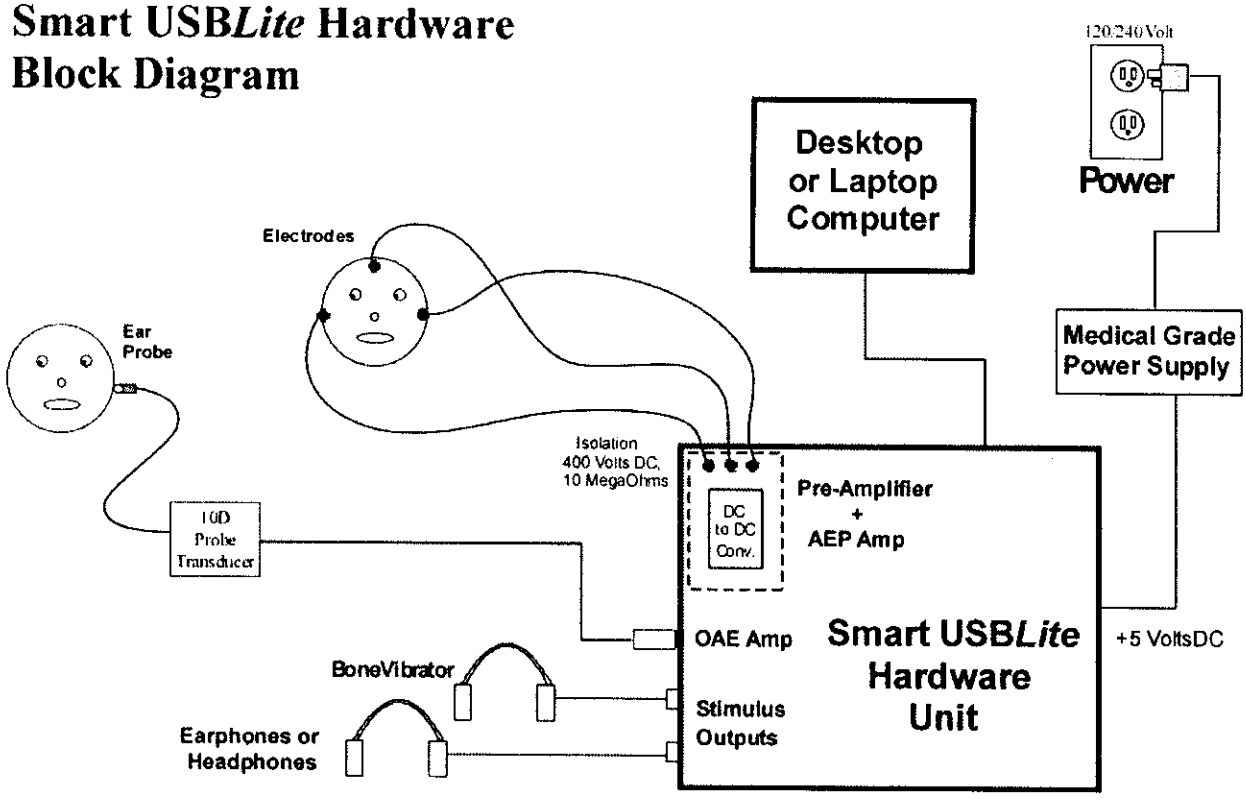

Figure 2: Block diagram of the Smart USB*Lite* system. The pre-amplifier electronics are embedded inside the receiver unit so there is no separate pre-amplifier unit. The patient cables are connected directly to the Smart USB*Lite* box. The patient is afforded protection by using a high voltage isolation DC-DC converter (rated up to 4000 volts DC, 10 Mega Ohms), as in K052060. The Smart USB*Lite* system derives its power from a +5V, 2A external medical grade power supply, which meets the appropriate safety requirements (IEC60601-1, UL2601-1, CSA601.1, EN60601-1, and EN60950).

Product Labeling

There have been no changes in intended use, advertisements, and directions for use due to the type of modifications to the original SmartEP, SmartScreener, SmartOAE, SmartTrOAE, and SmartEP-ASSR devices marketed by Intelligent Hearing Systems with FDA 510(k) clearance numbers K904926, K925648, K964426, K023859, and K031051 (respectively). The only changes in product labeling between the predicate device(s) and the device under current Special 510(k) review are in the electrical rating label, which includes a change in the reference model number (M011120) and the power specifications. Both changes have resulted from the modifications mentioned in this Special 510(k). The electrical rating label for the Smart USB*Lite* box is shown in the figure below.

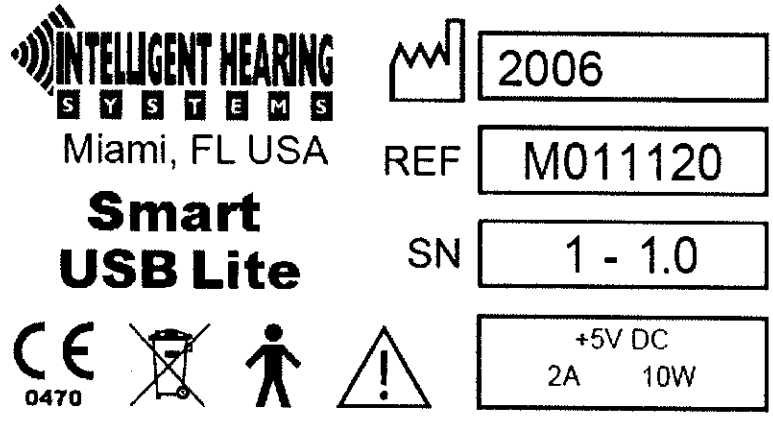

Figure 3: Electrical rating label for the Smart USB*Lite* box.

Declaration of Conformity:

As required by our risk analysis, all verification and validation activities have been performed for the Smart USB*Lite* device by designated individuals at Intelligent Hearing Systems. The results have demonstrated that all predetermined acceptance criteria have been met, in accordance with our ISO-13485 quality system. All records, including Device Master Records and Design History Files, are available for review upon request.

Edward Miskiel, Ph.D.
President & CEO

5/23/06

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 6 2006

Intelligent Hearing Systems
c/o Mr. Edward Miskiel
6860 S. W. 81st St.
Miami, FL 33143

Re: K061443
Trade/Device Name: Smart USBLite (with SmartEP, SmartScreener, SmartOAE, SmartTrOAE, & SmartEP-ASSR)
Regulation Number: 21CFR 874.1050
Regulation Name: Audiometer
Regulatory Class: II
Product Code: GWJ; EWO; GWL
Dated: May 23, 2006:
Received: May 24, 2006

Dear Mr. Miskiel:

This letter corrects our substantially equivalent letter of June 23, 2006.

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 (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); 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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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

510(k) Number (if known): K061443

Device Name: **Smart USB*Lite*** (with options of SmartEP, SmartScreener, SmartOAE, SmartTrOAE, & SmartEP-ASSR)

Indications for Use:

The intended use of the Smart USB*Lite* device system is for the recording of auditory evoked potential, otoacoustic emissions, & auditory steady-state evoked potential data. The product is intended to be used as a diagnostic aid in auditory and hearing related disorders, as an objective measure of cochlear function, and as an adjunctive tool in the estimation of behavioral hearing thresholds on patients of all ages.

The Smart USB*Lite* system combines the following FDA 510(k) previously cleared devices into a repackaged, smaller-sized, single, integrated unit: SmartEP (K904926), SmartScreener (K925648), SmartOAE (K964426), SmartTrOAE (K023859), SmartEP-ASSR (K031051), and Opti-Amp DC-Powered (K052060).

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

The anatomical sites of contact are:

(1) The patient's scalp and possibly other body sites with the contact objects being electrodes that are capable of measuring bio-potentials
(2) The patient's ear with the contact object being a sound delivery device eartip, headphone, ear probe, or ear cups.

Prescription Use X OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises
510(k) Number K061443

Prescription Use
(Per 21 CFR 801.109)