DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 29, 2017

Intelligent Hearing Systems
Edward Miskiel
President & CEO
6860 SW 81st St Street
Miami, Florida 33143

Re: K163326
Trade/Device Name: SmartEP
Regulation Number: 21 CFR 882.1900
Regulation Name: Evoked Response Auditory Stimulator
Regulatory Class: Class II
Product Code: GWJ, GWF, GWE, ETN
Dated: August 28, 2017
Received: August 29, 2017

Dear Mr. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/MedicalDevices/Safety/ReportaProblem/default.htm 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163326

Device Name
SmartEP

Indications for Use *(Describe)*

SmartEP is an evoked response testing and diagnostic device, that is capable of eliciting, acquiring, and measuring auditory, somatosensory, visual, and vestibular evoked myogenic potential data, as well as providing nerve stimulation and monitoring.

The intended use of the SmartEP device is to objectively record evoked responses from patients of all ages upon the presentation of sensory stimuli. The product is indicated for use as a diagnostic aid and adjunctive tool in sensory related disorders (i.e., auditory, somatosensory, visual, and vestibular) and in surgical procedures for inter-operative nerve monitoring.

The SmartEP system is intended to be used by trained personnel in a hospital, nursery, clinic, audiologist's, EP technologist's, surgeon's, or physician's office, operating room, or other appropriate setting.

The anatomical sites of contact for auditory evoked potential (AEP) testing are the patient's ear (with the contact object being a sound delivery eartip or headphone, or an ear probe and personal eartip, or earcup) and the patient's scalp and possibly other body sites (with the contact object being a bone transducer or electrodes that are capable of measuring bio-potentials).

The anatomical sites of contact for somatosensory evoked potential (SEP) testing are the patient's upper/lower limbs and head (with the contact object being two metal prongs or skin-surface electrodes connected to a constant-current stimulator probe) and to the patient's scalp and possibly other body sites (with the contact object being electrodes that are capable of measuring bio-potentials).

(Continued on next page.)

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163326

Device Name
SmartEP

Indications for Use *(Describe)*

(Continued from previous page.)

The anatomical sites of contact for visual evoked potential (VEP) testing are the patient's scalp and possibly other body sites (with the contact object being electrodes that are capable of measuring bio-potentials).

The possible anatomical sites of contact for nerve stimulation and monitoring testing are the patient's nerve tissue (with the contact object being sterile monopolar or bipolar nerve stimulator probe tips), the patient's tympanic membrane and cochlear promontory (with the contact object being a sterile stimulation needle electrode), and the patient's scalp and possibly other body sites (with the contact object being electrodes that are capable of measuring bio-potentials).

The anatomical sites of contact for vestibular evoked myogenic potential (VEMP) testing are the patient's ear (with the contact object being a sound delivery eartip or headphone, or an ear probe and personal eartip, or earcup) and the patient's head and neck and possibly other body sites (with the contact object being a bone transducer or electrodes that are capable of measuring bio-potentials).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Summary

Date Summary Prepared:

August 28, 2017

Submitter's Name and Address:

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

Contact Person:

Edward Miskiel, Ph.D.
Telephone: (305) 668-6102
Fax: (305) 668-6103

Device Name and Classification Panel Information:

Trade Name:	SmartEP	
Model:	M010000	
Common Names:	Evoked Response System, Nerve Stimulator/Monitor	
Classification Names:	Evoked Response Auditory Stimulator	(21 CFR 882.1900, GWJ)
	Evoked Response Electrical Stimulator	(21 CFR 882.1870, GWF)
	Evoked Response Photic Stimulator	(21 CFR 882.1890, GWE)
	Surgical Nerve Stimulator/Locator	(21 CFR 874.1820, ETN)

Predicate Devices:

The legally marketed devices to which equivalence is claimed:

Intelligent Hearing Systems SmartEP, Model M010000 (K070608)
GN Otometrics ICS Chartr EP 200 with VEMP (K143670)

Device Description

The SmartEP device records evoked potentials by using delivery of auditory, somatosensory, visual, or nerve sensory stimuli and using signal averaging techniques to extract the evoked potential from the uncorrelated electrical activity of the brain (electroencephalography or EEG) and muscles (electromyography or EMG). The device has options for Auditory Evoked Potentials (AEPs), Somatosensory Evoked Potentials (SEPs), Visual Evoked Potentials (VEPs), Vestibular Evoked Myogenic Potentials (VEMPs), and nerve stimulation and monitoring. The SEP, VEP, and nerve stimulation and monitoring functionality, operating principles, and intended uses are the same as on the predicate SmartEP device. On the SmartEP device with VEMP modality, the AEP modality has been modified to facilitate VEMP recording and analysis with optional biofeedback. The VEMP features added are comparable to those found in the ICS Chartr 200 predicate device. The VEMP modality does not provide a diagnosis. Diagnosis is made by a medical professional.

The SmartEP device is a Windows OS personal computer (PC) based system composed of software modules, an external main hardware unit, an optional biofeedback box, and peripheral stimulus delivery and recording components and accessories. The biofeedback box, stimulation, and recording devices are connected to the main hardware unit which is connected to the PC via a Universal Serial Bus cable. Software on the computer is used for the user interface to facilitate test parameter specification and for data display and analysis purposes.

The SmartEP with VEMP device has an optional biofeedback hardware accessory (VEMP feedback box) or uses a computer monitor for indicating EMG levels during VEMP testing. The VEMP feedback box has LEDs that indicate that the measured EMG level is either below the minimum value set by the user (Low – orange LED), or is between the minimum and maximum values set by the user (Satisfactory – green LED), or is above the maximum value as set by the user (High – orange LED). The computer monitor displays a bar graph and pictorial face that indicates that the measured EMG level is either below the minimum value set by the user (Low – small pink bar and sad face), or is between the minimum and maximum values set by the user (Satisfactory – medium green bar and happy face), or is above the maximum value as set by the user (High – large pink bar and sad face). Recording of VEMPs can be set to occur when the EMG level is within the user programmed satisfactory range.

Intended Use

The intended use of the SmartEP device is to objectively record evoked responses from patients of all ages upon the presentation of sensory stimuli. The product is indicated for use as a diagnostic aid and adjunctive tool in sensory related disorders (i.e., auditory, somatosensory, visual, and vestibular) and in surgical procedures for inter-operative nerve monitoring.

Comparison with Predicate Devices

Comparison of Indications for Use

Device Under Review: *SmartEP, M010000 with VEMP*
SmartEP is an evoked response testing and diagnostic device, that is capable of eliciting, acquiring, and measuring auditory, somatosensory, visual, and vestibular evoked myogenic potential data, as well as providing nerve stimulation and monitoring. The intended use of the SmartEP device is to objectively record evoked responses from patients of all ages upon the presentation of sensory stimuli. The product is indicated for use as a diagnostic aid and adjunctive tool in sensory related disorders (i.e., auditory, somatosensory, visual, and vestibular) and in surgical procedures for inter-operative nerve monitoring. The SmartEP system is intended to be used by trained personnel in a hospital, nursery, clinic, audiologist's, EP technologist's, surgeon's, or physician's office, operating room, or other appropriate setting. The anatomical sites of contact for auditory evoked potential (AEP) testing are the patient's ear canal (with the contact object being a sound delivery eartip or headphone, or an ear probe and personal eartip, or earcup) and the patient's scalp and possibly other body sites (with the contact object being a bone transducer or electrodes that are capable of measuring bio-potentials). The anatomical sites of contact for somatosensory evoked potential (SEP) testing are the patient's upper/lower limbs and head (with the contact object being two metal prongs or skin-surface electrodes connected to a constant-current stimulator probe) and to the patient's scalp and possibly other body sites (with the contact object being electrodes that are capable of measuring bio-potentials). The anatomical sites of contact for visual evoked potential (VEP) testing are the patient's scalp and possibly other body sites (with the contact object being electrodes that are capable of measuring bio-

potentials).

The possible anatomical sites of contact for nerve stimulation and monitoring testing are the patient's nerve tissue (with the contact object being sterile monopolar or bipolar nerve stimulator probe tips), the patient's tympanic membrane and cochlear promontory (with the contact object being a sterile stimulation needle electrode), and the patient's scalp and possibly other body sites (with the contact object being electrodes that are capable of measuring bio-potentials).

The anatomical sites of contact for vestibular evoked myogenic potential (VEMP) testing are the patient's ear canal (with the contact object being a sound delivery eartip or headphone, or an ear probe and personal eartip, or earcup) and the patient's head and neck and possibly other body sites (with the contact object being a bone transducer or electrodes that are capable of measuring bio-potentials).

Predicate Device: *SmartEP, M010000* (K070608)

SmartEP is an evoked response testing and diagnostic device, that is capable of eliciting, acquiring, and measuring auditory, somatosensory, and visual evoked potential data, as well as providing nerve stimulation and monitoring.

The intended use of the SmartEP device is to objectively record evoked responses from patients of all ages upon the presentation of sensory stimuli. The product is indicated for use as a diagnostic aid and adjunctive tool in sensory related disorders (i.e., auditory, somatosensory, visual) and in surgical procedures for inter-operative nerve monitoring.

The SmartEP system is intended to be used by trained personnel in a hospital, nursery, clinic, audiologist's, EP technologist's, surgeon's, or physician's office, operating room, or other appropriate setting.

The anatomical sites of contact for auditory evoked potential (AEP) testing are the patient's ear canal (with the contact object being a sound delivery eartip or headphone, or an ear probe and personal eartip, or earcup) and the patient's scalp and possibly other body sites (with the contact object being a bone transducer or electrodes that are capable of measuring bio-potentials).

The anatomical sites of contact for somatosensory evoked potential (SEP) testing are the patient's upper/lower limbs and head (with the contact object being two metal prongs or skin-surface electrodes connected to a constant-current stimulator probe) and to the patient's scalp and possibly other body sites (with the contact object being electrodes that are capable of measuring bio-potentials).

The anatomical sites of contact for visual evoked potential (VEP) testing are the patient's scalp and possibly other body sites (with the contact object being electrodes that are capable of measuring bio-potentials).

The possible anatomical sites of contact for nerve stimulation and monitoring testing are the patient's nerve tissue (with the contact object being sterile monopolar or bipolar nerve stimulator probe tips), the patient's tympanic membrane and cochlear promontory (with the contact object being a sterile stimulation needle electrode), and the patient's scalp and possibly other body sites (with the contact object being electrodes that are capable of measuring bio-potentials).

Predicate Device: ICS *Chartr EP 200 with VEMP* (K143670)

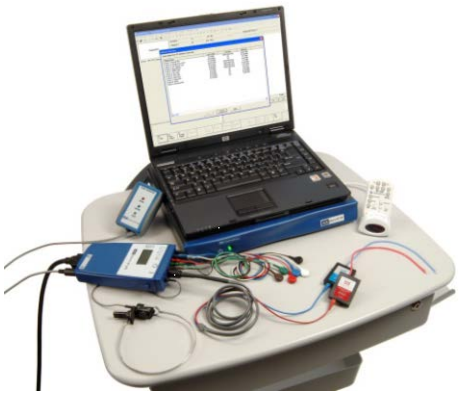
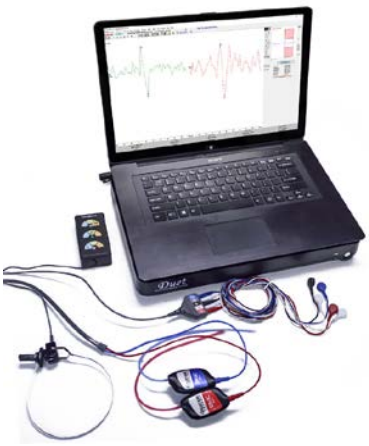
The ICS Chartr EP 200 with VEMP is indicated for auditory evoked potential testing as an aid in assessing hearing loss and lesions in the auditory pathway. The Vestibular Evoked Myogenic Potential is indicated for vestibular evoked potential testing as an aid in assessing vestibular function in adult patients. The device is to be used only by qualified medical personnel with prior knowledge of the medical and scientific facts underlying the procedure.

Intelligent Hearing Systems considers that the different phrasings in the indications for use are not critical to the intended use of the device and do not affect the safety and effectiveness of the device when used as labelled.

Comparison of Technological Characteristics

The SEP, VEP, and nerve stimulation and monitoring technological characteristics are the same as on the predicate SmartEP device (K070608). With the modified SmartEP with VEMP device, the AEP modality has been modified to facilitate VEMP recording and analysis with optional biofeedback.

Comparisons of technological characteristics with respect to VEMP testing of the SmartEP device with the GN Otometrics ICS Chartr EP 200 with VEMP predicate device (K143670) are given in the table below:

Parameter for Comparison	**Predicate Device** ICS *Chartr EP 200 with VEMP* (K143670) [VEMP Modality]	**Device Under Review** *SmartEP* [VEMP Modality]	**Impact of Difference(s) on Safety and Effectiveness** [Blank if No Difference]
VEMP Testing Modality	System features for VEMP testing	Same	
Configuration/ Hardware Implementation	Windows OS personal computer-based system composed of software modules, an external main hardware unit, and peripheral stimulus delivery and recording components and accessories (Universal Serial Bus interface)	Same	
Power	AC line power	Same	
Energy Used and/or Delivered	Stimulation of vestibular/auditory system with auditory stimuli	Same	
Configuration Photo			
Size/Weight	<u>Chartr EP 200 main unit:</u> 4.9cm x 34.2cm x 28.7cm (2in x 13.6in x 11.3in), 2.7kg (5lbs 7oz) <u>Chartr EP 200 preamplifier:</u> 3cm x 9.9cm x 16.4cm (1.19in x 3.88in x 6.44in), 0.27kg (9.5oz)	<u>Main hardware unit (includes internal preamplifier):</u> 4.76cm x 38.20cm x 25.00cm (1.87in x 15.04in x 9.84in), 1.13kg (2.50lbs)	Differences in the dimensions/weight of these components have no impact on safety or effectiveness.

VEMP Biofeedback	Enclosure with three LEDs for indicating that EMG level is either below the set minimum value, or between the set minimum and maximum values, or is above the set maximum value	Same with optional biofeedback display on computer monitor	
VEMP Feedback Box Photo			Differences in the color of the feedback boxes have no impact on safety or effectiveness.
VEMP Feedback Box Size/Weight	2.9cm x 6.2cm x 9.5cm (1.13in x 2.44in x 3.75in), 0.13kg (4.5oz)	2.50cm x 5.00cm x 10.00cm (0.98in x 1.97in x 3.94in), 0.1kg (2.9oz)	Differences in the size/weight of the feedback box have no impact on safety or effectiveness.
Human Factors	Personal computer software user interface Simple, easy-to-follow instructions	Same	
Biocompatibility	Assumed all patient-contacting accessories for VEMP testing are biocompatible	All patient-contacting accessories used with the SmartEP device for VEMP testing are biocompatible These accessories have either received FDA market clearance by their respective manufacturers, or are pre-amendment devices (i.e., sold prior to May 28, 1976), or are Class I devices exempt from the 510(k) process (e.g., earphone cushions/tips for audiometric testing per CFR 874.1100)	Since both devices use biocompatible patient-contacting accessories, there is no impact on safety or effectiveness.
Sterility	None Required	Same	
Safety Standards	EN60601-1 + A1 + A2 EN60601-1-2	Same	

Performance Testing Data

The modified SmartEP device conforms to the following standards:

- ES60601-1, Edition 3.1, 2012, "Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance." 2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012. (FDA Recognition Number 19-4)
- IEC60601-1-2, Edition 3.0, 2007, "Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests." (FDA Recognition Number 19-1)
- IEC60601-1-6, Edition 3.1, 2013, "Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability." (FDA Recognition Number 5-89)
- IEC62366, Edition 1.0, 2014, "Medical Devices - Part 1: Application of Usability Engineering to Medical Devices." (FDA Recognition Number 5-87)
- IEC60601-2-40, Edition 1.0, 1998, "Medical Electrical Equipment, Part 2-40: Particular Requirements for the Safety of Electromyographs and Evoked Response Equipment."
- IEC60601-1, Edition 2.0, 1995, "Medical Electrical Equipment, Part 1: General Requirements for Safety." 1988 and A1:1991 and A2:1995

The modified SmartEP device meets the requirements of the FDA guidance document "Premarket Notification Review Guidance for Evoked Response Stimulators" (FDA Document Number 593).

Verification and validation testing was performed on the SmartEP device to ensure that the output parameters meet the design input specifications and that the device meets its intended uses. The functionality of the VEMP testing features were verified through bench testing using different input signals and user-settings. The operation of the VEMP testing modality of the SmartEP device was validated and proved to be equivalent to the operation of the VEMP testing modality of the ICS Chartr EP 200 with VEMP predicate device (K143670).

The operation of the optional VEMP feedback box accessory and the optional computer monitor for biofeedback (indication of measured EMG levels) were verified to be accurate with different user-specified voltage monitoring settings and different voltage levels supplied to the device amplifier inputs. The operation of the optional VEMP feedback box accessory for the modified SmartEP device proved to be equivalent to the operation of the optional VEMP feedback box accessory for the ICS Chartr EP 200 with VEMP predicate device (K143670).

All instrument-measureable parameters for the SmartEP device were acquired with calibrated instruments traceable to NIST standards.

Clinical Testing Summary

Two studies were performed with using the SmartEP with VEMP device to confirm VEMP recording repeatability and reproducibility.

In the first study, P1 latency values from cVEMP recordings acquired from 215 normal subjects who were tested on two different days were analyzed. There were no statistically significant differences in P1 latency values acquired from the same subjects on different days and there were no statistically

significant differences in P1 latency values obtained from different subjects tested at two different test locations. In addition, the IQR (75^{th} – 25^{th} percentile) P1 latency values were also low, indicating a clustering of values near the median.

The second study was performed to confirm the repeatability of cVEMP and oVEMP waveforms. Right and left side cVEMP and oVEMP recordings were acquired from ten adult normal subjects. Subjects were tested in two test sessions on separate dates. The subject and equipment positions were changed for each session in order to simulate different testing locations and configurations. The acquisition parameters are listed in the table below:

Acquisition Parameters for cVEMP and oVEMP recordings

	cVEMP	oVEMP
Transducer	Insert Earphones	Insert Earphones
Stimulus	500Hz Blackman	500Hz Blackman
Intensity	95 dBnHL	95 dBnHL
Polarity	Rarefraction	Rarefraction
Rate	5.1	5.1
Number of Channels	2	2
Sweeps Total	500	500
Gain	5k	100k
High Pass Filter	10 Hz	10 Hz
Low Pass Filter	1 kHz	1 kHz
Sampling Rate	5 kHz	5 kHz

Test-Retest Repeatability based on the cross correlation measures between two sets of 250 sweeps acquired within each session are presented in the two tables below.

Correlation cVEMP waveforms (5-35 ms) - Session 1

	Left Side	Right Side
Mean:	0.911	0.915
Median:	0.928	0.932
IQR (75^{th} – 25^{th} percentile)	0.103	0.047

Correlation of cVEMP waveforms (5-35 ms) - Session 2

	Left Side	Right Side
Mean:	0.921	0.941
Median:	0.943	0.956
IQR (75^{th} – 25^{th} percentile)	0.076	0.053

Correlation oVEMP waveforms (4-20 ms) - Session 1

	Left Side	Right Side
Mean:	0.956	0.944
Median:	0.972	0.966
IQR (75^{th} – 25^{th} percentile)	0.049	0.083

Correlation oVEMP waveforms (4-20 ms) - Session 2

	Left Side	Right Side
Mean:	0.955	0.951
Median:	0.969	0.969
IQR ($75^{th} – 25^{th}$ percentile)	0.040	0.055

Based on the mean and median cross correlation measures obtained within each session, the results indicate a high degree of test-retest repeatability for both cVEMPs and oVEMPs. The IQR ($75^{th} – 25^{th}$ percentile) values were also low, indicating a clustering of values near the median.

Test Reproducibility based on the cross correlation measures between grand averages of 500 sweeps acquired across two sessions are presented in the table below.

Correlations of cVEMP waveforms - Session 1 vs Session 2

	Left Side	Right Side
Mean:	0.868	0.847
Median:	0.883	0.873
IQR ($75^{th} – 25^{th}$ percentile)	0.084	0.117

Correlations of oVEMP waveforms - Session 1 vs Session 2

	Left Side	Right Side
Mean:	0.940	0.902
Median:	0.971	0.950
IQR ($75^{th} – 25^{th}$ percentile)	0.062	0.022

Based on the mean and median cross correlation measures obtained across sessions, the results indicate a high degree of test reproducibility for both cVEMPs and oVEMPs. The IQR ($75^{th} – 25^{th}$ percentile) values were also low, indicating a clustering of values near the median. The reproducibility results indicate that subject position and equipment position did not affect the results.

In the 510(k) Summary for the predicate ICS Chartr EP 200 with VEMP device (K143670), the following data correlation values were reported in the table below.

Correlation values for predicate device (K143670)

	cVEMP (5 - 35ms)		oVEMP (4 - 20 ms)	
	Right	Left	Right	Left
Mean	0.915	0.916	0.926	0.93

The mean correlation values for both cVEMP and oVEMP recordings obtained the SmartEP with VEMP device for both test-retest repeatability and reproducibility are similar or higher than those reported for the ICS Chartr EP 200 with VEMP device.

Substantial Equivalence

Based on the comparison of technological characteristics and performance testing data, the modified SmartEP device is substantially equivalent with respect to Vestibular Evoked Myogenic testing to the ICS Chartr EP 200 with VEMP device (K143670), and is equivalent to the predicate SmartEP device (K070608) with respect to Auditory, Somatosensory, and Visual Evoked Potentials, and nerve stimulation and monitoring.

Conclusions

Based on design controls, comparison of technological characteristics, and performance testing data, the modified SmartEP device is as safe and effective as, and is substantially equivalent to the identified predicate devices.