May 6, 2022

WAVi Co.
David Jones
Consultant
3459 Ringsby Ct. Ste. #305
Denver, Colorado 80216

Re: K213900
Trade/Device Name: WAVi SCAN EEG System and Accessories
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ, GWJ, OLT
Dated: December 13, 2021
Received: December 14, 2021

Dear David Jones:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for
Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K213900

Device Name
WAVi SCAN EEG System and Accessories

Indications for Use *(Describe)*
WAVi SCAN EEG System is intended for the acquisition, display, and storage of electrical activity of a patient's brain including electroencephalograph (EEG) and event-related potentials (ERP) obtained by placing two or more electrodes on the head to aid in diagnosis.

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.

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K213900 WAVi™ SCAN EEG System
Traditional 510(K) Summary

Submitted by: WAVi Co.
3459 Ringsby Ct. Ste. #305
Denver, CO 80216
720-203-6970

Contact Person: David Jones
(281)989-8515
djones3016@hotmail.com

Date Prepared: May 5, 2022

Trade Name: WAVi™ SCAN EEG System and Accessories (Accessories are the WAVi™ Headset and WAVi™ eSoc™ Single Use Electrode Contacts, **K162460**)

Common Name: EEG Amplifier

Product Code(s): GWQ (Primary - full-montage standard electroencephalograph),
GWJ (stimulator, auditory, evoked response)
OLT (non-normalizing quantitative electroencephalograph software)

Regulation: 21 CFR § 882.1400

Classification: Class II

Classification Name: Electroencephalograph

Predicate Devices:

510(k) Number	Trade Name
K171781	eVox System Evoke Neuroscience 200 Valencia Dr. Suite 109 Jacksonville. NC 28546
K143233	Mitsar-EEG Nova Tech EEG 8503 E. Keats Avenue Mesa, AZ 85209
K141316	COGNISION™ EEG/EP SYSTEM Neuronetrix Solutions 1044 E. Chestnut Louisville KY, 40204

Device Description:

WAVi™ SCAN EEG system (WAVi™ SCAN 1.0) is intended for the acquisition, display, and storage of electrical activity of a patient's brain including electroencephalograph (EEG) and event-related potentials (ERP) obtained by placing two or more electrodes on the head to aid in diagnosis

The medical system includes the "WAVi™ EPU" (Electronic Processing Unit), an EEG amplifier intended to be used with EEG accessories cleared in **K162460** and a computer (laptop computer or tablet device with internal battery and power cord).

The hardware and ancillary components used in conjunction with WAVi™ SCAN 1.0 include an EEG cap, the WAVi™ EPU, headphones, a Subject Response Device and a Base Station laptop computer. The software on the Base Station laptop computer is intended for device programming.

The WAVI EEG System's software includes electronic versions of standardized clinical assessment tools related to psychiatry and neuropsychological evaluation but are provided for convenience and are to be used in accordance with the assessment tools' specific general instructions. These tools do not interact with any other of the EEG system's hardware and software measures and are stand alone.

Intended Use:

WAVi™ SCAN is intended for the acquisition, display, and storage, of electrical activity of a patient's brain including electroencephalograph (EEG) and event-related potentials (ERP) obtained by placing two or more electrodes on the head to aid in diagnosis.

Technological Characteristics:

WAVi™ SCAN EEG system consists of two software components:

- Base Station laptop computer software: pre-loaded WAVi™ SCAN 1.0, and
- Firmware running on the WAVi™ EPU ((PN SW-MSP43)).

The Base Station laptop is running on a Windows Operating System and is paired with the EPU through a USB cable. WAVi™ SCAN software runs on the Base Station computer and has a graphic user interface that allows the clinician to set up a patient and create a new patient record, conduct a study to collect EEG and ERP data, view live EEG and ERP data on the Base Station monitor, and export recorded data to a file.

Firmware for WAVi™ SCAN resides on the EPU. The purpose of the firmware is to acquire electrophysiology data from the patient and transmit it to the Base Station.

The EPU operational mode is controlled via the WAVi™ SCAN software. In addition to 19 channels of EEG recording the device includes a mode to measure the cap electrode impedances. This is useful for determining if the electrodes are making a good electrical connection with the scalp at each electrode location.

The primary software outputs are EEG and ERP data files. These data files are written as floating point numbers in binary format, which represent the electrical potential on each of the 19 EEG channels in microvolts. WAVI's qEEG outputs includes Coherence, delta, theta, alpha, beta Power, Audio P300 Delay and Voltage, and Physical Reaction Time.

The EPU amplifier device does not come in direct contact with patients. Accessories that contact patients such as the EEG electrode cap are the same as used with legally marketed devices or are comprised of the same materials as legally marketed accessories.

WAVi™ SCAN is intended for prescription use in any healthcare, medical, or athletic or sports clinics, or outside of medical facilities such as in the sports arena under the supervision of a physician.

The device is not sterile.

Substantial Equivalence

The WAVi™ SCAN EEG system is a portable, non-sterile, non-invasive, non-radiation emitting, point of care, electroencephalogram (EEG) devices, and is intended for the acquisition, display, and

storage, of electrical activity of a patient's brain including electroencephalograph (EEG) and event-related potentials (ERP) obtained by placing two or more electrodes on the head to aid in diagnosis.

The WAVi™ SCAN EEG system is substantially equivalent to the predicate devices in the following manner:

- Same intended use
- Same operating principle
- Same fundamental scientific technology
- Same or substantially equivalent materials, including headset and electrodes.

There are no technological differences between the WAVi™ SCAN EEG system and the predicates that raise different questions of safety and effectiveness, and the proposed differences have been addressed via performance testing. Therefore, the WAVi™ SCAN EEG system is substantially equivalent to the predicate device.

The following table compares the technological characteristics of WAVi Scan to those of the predicate devices in order to demonstrate Substantial Equivalence (SE).

	K213900 **Subject Device** **WAVi Scan**	**K171781** **eVox System**	**K143233** **MITSAR-EEG**	**K141316** **Cognision EEG/EP System**	**Remarks**
Principle of Operation	The WAVi Scan device is used for acquisition of physiological signals using two or more channels of electroencephalography (EEG) from the scalp. It consists of the WAVi Scan amplifier (EPU), a laptop or tablet computer (base station), a patient EEG cap accessory, subject response button, earphones, and a charging cord. The WAVi Scan EPU and software provide a means to: a) initiate a study, track user EEG and ERP data and enter text or questionnaire information, b) acquire and save signals to the memory of the device,	The eVox System device is used for acquisition of physiological signals using two or more channels of electroencephalography (EEG) from the scalp. It consists of an eVox amplifier, a laptop computer (base station), a patient EEG cap, subject response button, ear buds, and a charging cord. The eVox amplifier and software provide a means to: a) initiate a study, track user EEG and ERP data and enter text or questionnaire information, b) acquire and save signals to the memory of the device,	The Mitsar EEG consists of biosignal amplifier, USB cable, USB dongle and software. The medical system includes "Mitsar EEG" device and computer (stationary PC with uninterruptible power supply (UPS) or laptop with internal battery). The Mitsar EEG device is an amplifier which receives patient EEG data from a patient EEG cap or EEG electrodes.	The COGNISION EEG/EP System is a combination device for reduced montage recording and display of electroencephalographic (EEG) and evoked potentials (EP) test data. The system uses elastic bands to accurately position 10 electrode pods arou*nd* the head. EEG signal amplification, conditioning, and A/D conversion is performed by electronic circuits closely coupled to the electrode pods through short flexible printed wires. The headset is connected by a cable to a handheld control unit and data acquisition	Similar; All of these devices: -use skin coupling methods through electrodes which transmits patient EEG and ERP from the surface of the scalp to an amplifier, -use a wired connection between the amplifier and electrodes, -convert the analog data into digital data which are transmitted to a base station (computer), -transmit data to a base station computer, - display and store the data on the base station and allow the user to export the data to a file.

	K213900 **Subject Device** **WAVi Scan**	**K171781** **eVox System**	**K143233** **MITSAR-EEG**	**K141316** **Cognision EEG/EP System**	**Remarks**
	c) transmit signal data from the device, d) Visually inspect the acquired signal. e) Manage Event related Potentials (EEG) from the scalp.	c) transmit signal data from the device, d) Visually inspect the acquired signal. e) Manage Event related Potentials (EEG) from the scalp.		box (HCU). The HCU communicates via a wireless data link to a Window PC to stream EEG data. Software on the PC is used to setup the tests and view and evaluate the resultant test data using standard EEG/EP display methods.	
Patient population	All age groups	All age groups	All age groups	Adults	Similar
Use environment	Intended for use in any healthcare, medical, or athletic or sports clinics, or outside of medical facilities such as in the sports arena under the supervision of a physician. Also, investigations can be performed outside of healthcare facilities, as long as they are led by qualified medical personnel.	Intended for use in any healthcare, medical, or athletic or sports clinics, or outside of medical facilities such as in the sports arena under the supervision of a physician. Also, investigations can be performed outside of healthcare facilities, as long as they are led by qualified medical personnel.	Intended for use in Functional diagnostics wards and departments at out-patient clinics, hospitals, health research institutes, health centers and other medical institutions. Also, investigations can be performed outside of healthcare facilities, as long as they are led by qualified medical personnel.	Physicians' Offices	Similar
Regulatory Classification	Class II	Class II	Class II	Class II	

	K213900 **Subject Device** **WAVi Scan**	**K171781** **eVox System**	**K143233** **MITSAR-EEG**	**K141316** **Cognision EEG/EP System**	**Remarks**
Biocompatibility	N/A	Per ISO 10993-1	Per ISO 10993-1	Per ISO 10993-1	Similar; The patient-contacting components have been previously cleared in **K162460** and ISO 10993-1 for these components was covered in that submission
Intended Use	WAVi Scan is intended for the acquisition, display, and storage, of electrical activity of a patient's brain including electroencephalograph (EEG) and Event-related Potentials (ERP) obtained by placing two or more electrodes on the head to aid in diagnosis.	The eVox System is intended for the acquisition, display, and storage, of electrical activity of a patient's brain including electroencephalograph (EEG) and Event-related Potentials (ERP) obtained by placing two or more electrodes on the head to aid in diagnosis.	The Mitsar-EEG is intended to acquire, display and store the electrical activity of a patient's brain by placing two or more electrodes on the head to aid in diagnosis.	The COGNISION system is a combination device for reduced montage recording and display of electroencephalograph (EEG) and evoked potentials (EP) test data.	Same
ERP Stimulus Modality	Auditory	Auditory; Visual	None	Auditory	Similar
System Components	WAVi Scan EEG System consists of: • a laptop computer (base station), • an amplifier (WAVi EPU),	eVox System consists of: • an eVox amplifier, • a laptop computer (base station), • a patient EEG cap,	"Mitsar EEG" consists of: •biosignal amplifier, • computer (stationary PC with uninterruptible power supply (UPS)	COGNISION™ consists of: • Headset • Auditory stimulator • Handheld Control Unit	Similar

	K213900 **Subject Device** **WAVi Scan**	**K171781** **eVox System**	**K143233** **MITSAR-EEG**	**K141316** **Cognision EEG/EP System**	**Remarks**
	• subject response button, • WAVi SCAN EEG software, • earphones, and • charging cord. Accessories: WAVi Cap and eSoc K162460	• subject response button, • ear buds, • and a charging cord.	• or laptop with internal battery) • USB cable, • USB dongle • and software	(HCU) including Interface Software • Connecting Headset cable between the *headset* and the handheld control unit	
ERP Paradigm (Auditory and Visual Stimuli)	P300 Oddball - Single Stimulus - Single Deviant	P300 Oddball - Single Stimulus - Single Deviant - 2 Deviant - Active and Passive	None	P300 Oddball - Single Stimulus - Single Deviant - 2 Deviant - Active and Passive	Similar
ERP Task Response	User Buttons	User Buttons	None	User Buttons	Similar
Skin Coupling	N/A	Custom Electrode Band and Gel	Custom Electrode Band and Gel	HydroDot Biosensor	Similar; WAVi SCAN can be used with any 510(k) cleared EEG gel
Sterile	No	No	No	No	Similar
Single Use	No	No	No	No	Similar
Shelf life	Durable Good	Durable good	Durable good	Durable good	Similar
Typical Biopotential Signals Recorded	Electroencephalography (EEG), EP/ERP	Electroencephalography (EEG), EP/ERP	Electroencephalography (EEG)	Electroencephalography (EEG), EP/ERP	Similar; WAVi Scan, eVox and Cognision record EEG and EP/ERP. Mitsar does not have EP/ERP modality.

	K213900 **Subject Device** **WAVi Scan**	**K171781** **eVox System**	**K143233** **MITSAR-EEG**	**K141316** **Cognision EEG/EP System**	**Remarks**
Number of Signal Recording Channels	Up to 21	Up to 21	Up to 21	Up to 10	Similar
Recording Channels Location and Positioning Systems	10- 20 System	Fz,Cz,Pz,F3,P3,F4,P4 Utilizing elastic bands using distance ratios consistent with the 10-20 System	Fz,Cz,Pz,F3,P3,F4,P4 Utilizing elastic bands using distance ratios consistent with the 10- 20 System	Fz,Cz,Pz,F3,P3,F4,P4 Utilizing elastic bands using distance ratios consistent with the 10-20 System	Similar; WAVi Scan, eVox, Mitsar and Cognision call for the same electrode placement configuration
Impedance Test	Yes	Yes	Yes	Yes	Similar
Amplifier Input Impedance	>= 1 GΩ	> 10 MΩ	> 200 MΩ	> 60 MΩ	Similar
Analog to Digital Conversion	24 Bit	24 Bit	16 Bit	16 Bit	Similar
Sampling Rate	250 Hz	250 Hz	500 Hz	125/250 Hz	Similar
Common mode rejection	>= 115 dB	>110 dB	>110 dB	>90 dB	Similar
Analysis Software	Embedded, commercially available, and user defined.	Embedded, commercially available, and user defined.	Embedded, commercially available, and user defined.	Embedded, commercially available, and user defined.	Similar
Interface with Amplifier	USB cable to PC	Class 2 Bluetooth® version 2.0 to PC	USB cable to PC	Bluetooth 2.0/4.0	Different; however, the lack of wireless connectivity does not raise different questions of safety and effectiveness

	K213900 **Subject Device** **WAVi Scan**	**K171781** **eVox System**	**K143233** **MITSAR-EEG**	**K141316** **Cognision EEG/EP System**	**Remarks**
Power Supply	USB cable	Li-Ion Battery, with USB cable for charging the battery.	USB cable	Li-Ion Battery	Similar
EEG input terminals	up to 19 channels	up to 19 channels	up to 21 channels	up to 7 channels	Similar
Resolution	24 bits	24 bits	16 bits	16 bits	Similar
Band Width	0.5 to 40 Hz	0.1 to 50 Hz	0.162-70 Hz	0.4 to 40 Hz	Similar; WAVi Scan meets the Frequency requirements of IEC 80601-2-26:2019 (0.5Hz-50 Hz)
Noise	< 3.0 µVp-p	2-3 uVp-p	< 1.5µVp-p	<1 uV RMS	The measured noise of <3uVp-p for WAVi Scan is well within the IEC 60601-2-26:2019 requirement of 6 uVp-p. Substantially Equivalent
Event Related Potentials (ERP) Type	Tones	Burst (White Noise)	None	Tones	Similar; WAVi uses tones, which is typical for oddball P300 and also has subjects respond to target stimuli that occur infrequently and irregularly within a series of standard stimuli.
Duration for ERP	50ms	100ms	None	50ms	Similar; 50- 100ms is a typical length for evoking an ERP.
Ear Sides	Both	Both	None	Unknown	Similar

	K213900 **Subject Device** **WAVi Scan**	**K171781** **eVox System**	**K143233** **MITSAR-EEG**	**K141316** **Cognision EEG/EP System**	**Remarks**
ERP Frequency range	1 kHz and 2.77 kHz, programmable from 440Hz-16kHz for research purposes	440 Hz-16kHz	None	Unknown	Similar; The WAVi Scan system generates a sound with a frequency range of 440Hz-16kHz which is sufficiently wide enough band for human hearing.
Intensity	0 to 85 dB	0 to 85dB	None	Unknown	Similar; The Maximum decibel level is 85dB, well below 125dB (low risk to user)
Noise Patterns	16.7% occurrence randomly distributed over a minimum of 4 minutes	12.5% occurrence randomly distributed over 10 minutes	None	10% occurrence within 10-60 minutes	Similar; This pattern is standard to elicit the desired number of ERPs as set by the user in selecting testing times.
Input Voltage Range	+/- 400mV	+/-150 mV	5 mV	Not stated	Similar
Safety Standards Compliance	IEC 60601-1-2:2014 IEC/EN 60601-1:2005+A1:2012 IEC 80601-2-26:2019	IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (or IEC 60601-1: 2012 reprint) EN 60601-1-2:2012 IEC 60601-2-26:2012	EN 60601-1:2005 EN 60601-1-2:2005 EN 60601-2-26	UL 60601-1:2003 EN60601-1-2/A1:2007 EN60601-1-2/A1:2007 EN 60601-2-26 IEC 60601-2-40	Similar
Operating Environment	0 to +45 °C, Relative humidity, 5% to 95% noncondensing	0 to +45 °C, Relative humidity, 5% to 95% noncondensing	Not Published	60 to 90 °F	Similar
Storage Environment	−20° to 45° C, Relative humidity, 5% to 95% noncondensing	−20° to 45° C, Relative humidity, 5% to 95% noncondensing	Not Published	Not published	Similar

Substantial Equivalence Discussion:

The subject and predicate devices have the same intended use and have similar technological characteristics pertaining to hardware, operating systems, software, features, and functions. Thus, the WAVi™ SCAN EEG system is substantially equivalent to the predicate device(s).

Performance Testing and Conformance to Standards

The WAVi™ SCAN 1.0 development and performance testing has met all performance specifications, product standards and national and international standards.

Extensive functional device testing and user testing has been performed with satisfactory results. Additionally, tests have been performed by accredited laboratories and show full compliance with standards IEC 80601-2-26:2019 Medical electrical equipment – Part 2: Particular requirements for the safety of electroencephalographs.

Clause	Requirement + Test	Results - Remarks
201.12.1.1 02	**Accuracy of signal reproduction**	**P**
	Input voltages in the ranges and varying at rates selected from "Scalp" and/or "Cerebral cortex or subdural locations" according to Table 201.102 ware reproduced on the output with an error of ≤ ±20 % of the nominal value of the output or ±10 μV, whichever is greater	**P**
	Compliance checked according to Fig.201.104	**P**
201.12.1.1 03	**Input dynamic range and differential offset voltage**	**P**
	With a d.c. offset voltage in the range of ±150 mV and differential input signal voltages of ±0,5 mV that vary at rates up to 12 mV/s, when applied to any LEAD WIRE, the time-varying output signal amplitude did not change by more than ±10 % over the specified range of d.c. offset.	**P**
201.12.1.1 04	**Input noise**	**P**
	The signal noise caused by the EEG amplifier and PATIENT CABLE did not exceed 6 μV peak-to-valley referred to the input (RTI)	**P**
	Compliance checked according to Fig.201.105	**P**
201.12.1.1 05	**Frequency response**	**P**
	ME EQUIPMENT meets the requirement for a frequency response (bandwidth) of at least 0,5 Hz to 50 Hz when tested with sinusoidal input signals.	**P**
	The output at 0,5 Hz and 50 Hz was within 71 % to 110 % of the output obtained with a 5 Hz sine wave input signal.	**P**
	Compliance checked according to Fig.201.104	**P**
201.12.1.1 06	**Common mode rejection**	**P**
	A 1 V r.m.s. signal at mains frequency (50 Hz/60 Hz) with 200 pF source capacitance, connected between earth and all LEAD WIRES connected together did not produce an output signal greater than 100 uV peak-to-valley over a 10 s period.	**P**
	In series with each ELECTRODE was a 10 kΩ resistor in parallel with a 47 nF capacitor and PATIENT CABLE specified by the MANUFACTURER were used.	**P**
	Compliance checked using Fig.201.105 with any mains frequency notch filter (if provided) turned off.	**P**
	The measured output amplitude was not be greater than 100 uV peak-to-valley	**P**

Performance Testing

Electrical Safety & Electromagnetic Compatibility (EMC)

The tests have been performed by accredited laboratories and show full compliance with standards below: ANSI AAMI 60601-1: 2005 +A1:2012, Medical electrical equipment electrical equipment- Part 1: General requirements for basic safety and essential performance (FDA recognition # 19-4).

The tests have been performed by the accredited laboratories and show full compliance with standards below. The device under consideration has passed the tests according to IEC 60601-1 and IEC 60601-1-2:2014 (4th Edition) General requirements for basic safety and essential performance – Collateral Standard Electromagnetic disturbances – Requirements and tests (FDA recognition # 19-1)

Table II EMI Testing IEC 60601-1-2:2014 (4th Edition)			
Test Description	**Specification**	**Notes**	**Results**
Radiated Emissions	EN 55011:2009+A1:2010	Class B 30MHz – _1GHz	Conforms
Electrostatic Discharge Immunity	IEC 61000-4-2:2008	Contact discharge: ±8kV and Air Discharge: ±2kV, ±4kV, ±8kV, ±15kV	Conforms
Radiated Electromagnetic Field Immunity	IEC 61000-4-3:2006	80MHz to 2.7GHz @ 10V/m 80% AM at 1kHz	Conforms
Proximity Fields from RF Wireless	IEC 61000-4-3:2010	Table 9	Conforms
Magnetic Field Immunity	IEC 61000-4-8:2009	30A/m @ 50Hz or 60Hz	Conforms