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

April 28, 2017

WAVi, Co.
David Jones
FDA Consultant
3535 S Irving St.
Englewood, Colorado 80110

Re: K162460
Trade/Device Name: WAVi™ Headset and WAVi™ eSoc™ Single Use Electrode Contacts
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: March 22, 2017
Received: March 31, 2017

Dear Mr. 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. 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)*
K162460

Device Name
WAVi™ Headset and WAVi™ eSoc™ Single Use Electrode Contacts

Indications for Use *(Describe)*
The WAVi Headset is intended for use in routine clinical and research settings where rapid placement of a number of EEG electrodes is desired.

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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510(k) SUMMARY

Submitted by: WAVi Co.
3535 S. Irving Street
Englewood, CO 80110
804-909-2389

Contact Person: David Jones
281-989-8515

Date Prepared: April 28, 2017

Proprietary Name: WAVi™ Headset and WAVi™ eSoc™ Single Use Electrode Contacts

Model Numbers: WH-100: XS Headset
WH-200: S Headset
WH-300: M Headset
WH-400: L Headset
WH-500: XL Headset

Common Name: EEG 10-20 Electrode Headset and Electrodes

Classification: Class II: 21 CFR § 882.1320

Classification Name: Cutaneous Electrode – GXY

Predicate Devices: Electro-Cap™ System (K112319)
Electro-Cap™ Intl., Inc.
1011 West Lexington Rd.
Eaton, OH 45320

Device Description:

The WAVi™ Headset is an EEG electrode positioning system used to quickly place the electrodes in a uniform and consistent manner in accordance with the international standard Ten-Twenty System (10-20) to acquire electrophysiological EEG signals from an individual to a suitable EEG data collection device.

The device consists of the WAVi™ Headset, WAVi™ eSoc™ Single Use and Tin Electrode Contacts; the head set comes in five models/sizes (XS, S, M, L, XL). This device is portable, non-sterile, non-invasive, non-radiation emitting, point-of-care use device for use in healthcare facilities and hospitals.

Device characteristics include the eSoc™ Single Use Electrode Contacts which are soaked in 0.9% Normal Saline which is unique as it serves as the electro-conductive material and patient contact allowing the brain's electrical signals to be read through an EEG data collection device. Typical set-up and procedure time is less than twenty minutes.

The device does not contain software, biologics, drugs, coatings or any claim of sterility.

The WAVi™ Headset, eSoc™ Single Use and Ear Electrode Contacts are made from well-established medical grade materials; the Headset is made from a proprietary EVA material with tin plated ring electrode ports for placement of the Nylon 101 WAVi™ eSoc™ Single Use Electrode Contacts, and two ear electrodes are also made from Tin. A wire harness is embedded between two layers of EVA and is attached to each electrode port. The wire harness exits the headset to a 32-pin connector port.

Intended Use:

The WAVi Headset is intended for use in routine clinical and research settings where rapid placement of a number of EEG electrodes is desired.

Technological Characteristics

The following is a side-by-side of the WAVi device compared to the Predicate:

Manufacturer	**WAVi Co.**	**Electro-Cap**
Trade Name	**WAVi Headset**	**Electro-Cap System (K780045)**
Indication for Use	The WAVi Headset is intended for use in routine clinical settings where rapid placement of a number of EEG electrodes is desired.	The Electro-Cap is intended for use in routine clinical settings where rapid placement of a number of EEG electrodes is desired.
Environmental Use	Electrophysiological	Electrophysiological
Target Patient	Adults and Children	Adults and Children
Where Used	On the head	On the head
Anatomical Contact Sites	Patient's skin (scalp)	Patient's skin (scalp)
Number of Contacts	22	2 to 256
Sterile	No	No
Size of Cap	Various- Extra Small to Extra Large	Various- Extra Small to Large
Style of Cap	Full Head Cap	Full Head Cap
Cap Material	EVA	Spandex
Location of Wiring	Inside Cap	Inside Cap
Type of Cables	Standard Ribbon Cable and Lead Wires	Standard Ribbon Cable and Lead Wires
Type of Electrode Drop	Detachable and Non Detachable	Detachable and Non Detachable
Electrode Material	Nylon 6/6 (101) and Pure Tin	Pure Tin
Electrode Placement System	The International 10-20 System is used as a basis for the electrode placement.	The International 10-20 System is used as a basis for the electrode placement.
Number of Recording Channels	19	19
Electrode Positions Utilized	Fp1, Fp2, F7, F3, Fz, F4, F8, T3, C3, Cz, C3, T4, T5, P3, Pz, P4, T6, O1, O2, A1, A2	Fp1, Fp2, F7, F3, Fz, F4, F8, T3, C3, Cz, C3, T4, T5, P3, Pz, P4, T6, O1, O2, A1, A2
Type of Connectors	D-Sub Connectors, Touch Proof Din Sockets and Special Connectors to Match EEG Equipment and Computers	D-Sub Connectors, Touch Proof Din Sockets and Special Connectors to Match EEG Equipment and Computers
Biocompatibility Testing	None was conducted	None was conducted

Performance Requirements	Needs to transmit electrophysiological signals from an individual to data collection devices. Does not transmit electrical current, nor are they intended to be used for stimulation.	Needs to transmit electrophysiological signals from an individual to data collection devices with a maximum impedance of 5K/Ohms. Does not transmit electrical current, nor are they intended to be used for stimulation.

The electrical activity of the brain is acquired through 0.9% Normal Saline soaked eSoc™ inserted into the electrode ports and connected through the Headset's wiring harness to the Patient Cable which is connected to the EEG device where brain activity may be recorded for evaluation.

Non-Clinical Testing:

The WAVi™ Headset and accessories are manufactured of medical grade materials including ethylene vinyl acetate (EVA), nylon 6/6 (101) and tin. Multiple 510 (k)'s have been cleared for each of these materials demonstrating no need for further biocompatibility testing.

The WAVi™ Headset and accessories' Quality Assurance testing includes visual inspection of the headset, label and labeling, dimensional verification, and individual electrode resistance of the components and finished product. The WAVi™ Headset and accessories meet all performance specifications.

The WAVi™ Headset and the Electro-Cap™ System were compared for sizing, electrode placement and labeling, and was found to be substantially equivalent.

The WAVi™ Headset and the Electro-Cap™ were also compared side-by-side on three test subjects using a Lexicor Neurosearch-24 Brain mapper (K915820); the spectral shape and maximum frequency of the corresponding WAVi Headset and Electro-Cap spectrums at each of the 10/20 EEG locations were consistently similar within each subject.

Substantial Equivalence

The WAVi™ Headset, WAVi™ eSoc™ Single Use and Tin Ear Electrode Contacts are portable, non-sterile, non-invasive, non-radiation emitting, point of care, electroencephalogram (EEG) devices, and is intended for use in routine clinical and research settings where rapid placement of a number of EEG electrodes is desired.

All non-clinical tests demonstrate that the WAVi™ Headset and accessories are as safe, as effective, and perform as well as or better than the legally marketed predicate device.

The WAVi™ Headset 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 other substantial or significant differences between the WAVi™ Headset and its' accessories and the predicate that would affect safety, effectiveness or performance, therefore the WAVi™ Headset and accessories' are substantially equivalent to the predicate device.