April 21, 2020

Wuhan Greentek Pty Ltd.
Yarong Liu
Rm 03-2, Floor 3, Dingye Bldg, Phase III International Enterprise Center, Special No.1
Guanggu Ave
Donghu New Technology Development Zone
Wuhan, Hubei, 430074 China

Re: K200162
Trade/Device Name: Disposable EEG Electrodes (MODEL: DL, E-CAP, FLEX-CAP)
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: January 1, 2020
Received: January 22, 2020

Dear Yarong Liu:

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 Vivek Pinto, PhD
Director
DHT5B: Division of Neuromodulation
and Physical Medicine 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)*
K200162

Device Name
Disposable EEG Electrodes (MODEL: DL, E-CAP, FLEX-CAP)

Indications for Use *(Describe)*
Disposable EEG Electrodes (MODEL: DL, E-CAP, FLEX-CAP) is intended for use in routine clinical 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: March 8, 2020

1. Submitter's Information

The submitter of this pre-market notification is:

Name:	Wuhan Greentek Pty Ltd
Address:	Room 03-2, Floor 3, Dingye Building, Phase III, International Enterprise Center, Special No.1, Guanggu Avenue, Donghu New Technology Development Zone, Wuhan, CHINA 430074
Contact person:	Yarong Liu
Title:	Manager
E-mail:	lyr@gtsensor.com
Tel:	+86-27-88185488

2. Device Identification

Trade/Device Name:	Disposable EEG Electrodes (MODEL: DL, E-CAP, FLEX-CAP)
Models:	DL, E-CAP, FLEX-CAP
Common Name	Disposable EEG Electrodes system
Regulation Number:	21 CFR 882.1320
Regulation Name:	cutaneous electrode
Regulation Class:	Class II
Product Code:	GXY

3. Predicate Device

510(K) number:	K112319
Trade Name:	Electro-Cap System
Common Name	EEG electrode positioning system
Manufacturer:	Electro-Cap International, Inc.
Regulation Number:	21 CFR 882.1320
Regulation Name:	cutaneous electrode
Regulation Class:	Class II
Product Code:	GXY

4. Device Description

Disposable EEG Electrodes includes three models: DL, E-CAP, FLEX-CAP.

The models E-CAP and FLEX-CAP are EEG electrode positioning systems used to place a number of EEG electrodes in a uniform and consistent manner on the head in order to transmit electrophysiological signals from an individual to data collection devices. The model E-CAP is made from spandex type material with silver/silver chloride-plated ABS electrodes in silicone base attached to the cap. The model FLEX-CAP is made from spandex type material with silver/silver chloride ink printed electrodes on PET in silicone base attached to the cap, the cap covering the entire scalp and is held in place with chin straps. The spandex type material holds the electrodes securely in position during an EEG recording. The electrodes on the caps connect to the EEG equipment either through an adapter cable or in some instances, special connector on match EEG equipment. The electrical activity of the brain is transferred via the electrolyte to the electrode and then to the EEG equipment for evaluation. The models E-CAP and FLEX-CAP have been built with the placement of 2-128 electrodes, the size of cap is from 26 to 66 cm.

The model DL is a silver/silver chloride-plated ABS electrode with shrink tubing and connector, which is used on the model E-CAP. In addition, model DL can be used alone on the scalp for EEG monitoring.
The electrodes on the Disposable EEG Electrodes (MODEL: DL, E-CAP, FLEX-CAP) are positioned according to the International Ten-Twenty System (10-20) of Electrode Placement. In addition, Disposable EEG Electrodes (MODEL: DL, E-CAP, FLEX-CAP) with as a few as 2 or as many as 128 electrodes, have been mounted in a place according to the 10-10 American Electroencephalographic Society positioning system. Disposable EEG Electrodes (MODEL: DL, FLEX-CAP, FLEX-CAP) can also be custom-made, in which the numbers of electrodes and placement of electrodes are made under an instruction from customs.

5. Indication for use

Disposable EEG Electrodes (MODEL: DL, E-CAP, FLEX-CAP) is intended for use in routine clinical settings where rapid placement of a number of EEG electrodes is desired.

6. Comparison to Predicate Device

Compared to the predicate devices, the subject device has same intended use, similar product design, and same performance effectiveness as the predicate device as summarized in the following table.

Feature	Subject device	Predicate device	Discussion
510(k) Number	-	K112319	-
Indication for Use	Disposable EEG Electrodes (MODEL: DL, E-CAP, FLEX-CAP) 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.	Same
Classification	Class II per 21CFR882.1320,	Class II per 21CFR882.1320,	Same

Regulation	cutaneous electrode	cutaneous electrode	
Product Code	GXY, Electrode, cutaneous	GXY, Electrode, cutaneous	Same
Environment of use	Electrophysiological	Electrophysiological	Same
Intended user	Neurologists	Neurologists	Same
Target patient	Adults and Children	Adults and Children	Same
Where used	On the head	On the head	Same
Number of contacts	2-128	2-256	The placement of the electrodes is according to the International (10-20) System of Electrode Placement or (10-10) American Electroencephalographic Society positioning system. The number of the electrodes in use is according to the needs of clinic practice. By using 19 electrodes and 32 electrodes (or 19 channels and 32 channels can meet majority needs, while using channels up to 128 can satisfy most medical applications as the predicate K112319 does. The disposable electrodes can adapt to most EEG equipment as the predicate K112319 does. Both of the subject device and the predicate device are applied to record EEG signals on patients' scalp, and the bioelectrical signals are in microvolts-level. The electrodes only transfer tiny bioelectrical signals to the EEG recording equipment. The doctors can read the signals according the channels assigned, such as 19 channels or 32 channels. The safety issue only concerns the bio-

			compatibility of the electrode materials, while the effectiveness mainly concerns the electrode surface materials. The number of electrodes in the products is irrelevant to the safety and also doesn't affect the effectiveness compared to predicate devices. Therefore, the difference in numbers of electrodes does not raise any new safety risk or effectiveness issue.
Size of Caps	Various – babies to large 26cm to 66cm	Various – babies to large 26cm to 66cm	Same
Style of Caps	Full head cap	Full head cap	Same
Ear Slits	Yes	Yes	Same
Cap material	Spandex	Spandex	Same
Electrode Mounts	Silicone	Polyethylene	The mount base used in the Disposable Electrodes is designed for fastening the electrodes on the cap fabric, and the base don't involve in the bioelectrical signal recording. Silicone is a common material used in medical device. The silicone mount base can be made soft than the base made by polyethylene in the predicate device. Therefore, by using silicone materials as the mount base offers more comfortable experience to the users. Furthermore, the silicone mount bases used in this Disposable Electrodes have passed the bio-compatibility test. Thus, the use of silicone as electrode mount base does not raise new safety and effectiveness issues.

Cable Length	0.1 m - 3.0 m	Various - 3 to 5 feet	The length of the cable in the Disposable electrodes is different from the predicate device but it doesn't raise new safety and effectiveness issue. Because the cable is used for transferring EEG signals (the tiny bioelectrical signal in ~ several ten microvolts peak to peak) from the patients' scalp to the data record devices. The cable is designed in conformance with AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (consolidated text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, mod).
Type of Cables	Standard ribbon cable and lead wires	Standard ribbon cable and lead wires	Same
Electrode Metal	1. FLEX-CAP: silver/silver chloride ink printed electrodes on PET (Polyethylene terephthalate) 2. DL and E-CAP: silver/silver chloride – plated ABS base	Pure tin, silver, silver/silver chloride, gold plated	Electrode material need to have good electrical conducting and non-polarized characteristic on the surface (low interface impedance). The predicate device has four electrode materials, but the best electrode material is silver/silver chloride as it possesses non-polarized surface. The surface material of disposable electrodes is silver/silver chlorides, which is printed or plated on plastic (PET, Polyethylene terephthalate or ABS). The plastic provides a supporting substrate, the surface silver/silver chloride provide electrode function as electrical conducting and low impedance as the one of the best electrodes in the predicate devices. These plastics don't

			contact to scalp and don't involve in bioelectrical signal recording either. Further, the electrodes with silver/silver chloride ink printed on PET substrate and silver/silver chloride plated on ABS substrate have passed bio-compatibility tests in accordance with ISO 10993-1 and as well as performance test in accordance with ASTM EC 12. The test result shows that subject device meets the performance requirements of FDA guidance, so the difference in materials does not raise new safety and effectiveness issues.
Type of Connectors	Touch-proof safety socket DIN42-802 (Φ=1.5mm)	D-Sub connectors, touch proof DIN sockets and special connectors on match EEG equipment and computers	The connector of the Disposable electrodes is actually a touch-proof safety socket DIN 42 802 (Φ=1.5mm) which is the same as the predicate device of Touch Proof DIN Sockets
Biocompatibility test	ISO 10993-1, ISO 10993-5, ISO 10993-10	None was conducted	The subject device has been performed biocompatibility test according to the FDA guidance, this difference does not raise any new safety or effectiveness.
Performance requirements	1. Resistance <100 Ω 2. AC impedance <2 kΩ (at 10 Hz) 3. DC offset voltage <100 mV 4. Combined offset instability and internal noise: <150 μV 5. Bias current tolerance <100 mV	Needs to transmit electrophysiological signals from an individual to data collection devices with a maximum impedance of 5 K/Ohms. Does not transmit electrical current, nor are they intended to be used for stimulation.	The subject device was performed electrode characterization test according to the FDA guidance, the performance of subject device met the requirements of FDA guidance “Cutaneous Electrodes for Recording Purposes - Performance Criteria for Safety and Performance Based Pathway”. we have done more details in tests according to the FDA guidance.

All the differences do not affect the safety and effectiveness of the subject device which is concluded after all the required testing, so there are no safety and effectiveness issues relating to the subject system.

7. Performance Data

Clinical test:

Clinical testing is not required.

Non-clinical data

Performance:

We performed electrical safety. The design of the Disposable EEG Electrodes (MODEL: DL, E-CAP, FLEX-CAP) is in conformance with subclause 8.5.2.3 of AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (consolidated text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, mod). We carried out the performance test and shelf life validation according to the <Cutaneous Electrodes for Recording Purposes - Performance Criteria for Safety and Performance Based Pathway: Draft Guidance for Industry and Food and Drug Administration Staff> and ANSI EC12-2000 Disposable ECG electrodes.

Biocompatibility:

1. ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
2. ISO 10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
3. ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

8. Conclusion

Based on the comparison with predicate device, our Disposable EEG Electrodes (MODEL: DL, E-CAP, FLEX-CAP) has the same intended use, structure, and technologies, which is substantially equivalent to predicated device.