January 19, 2023

Shenzhen Med-link Electronics Tech Co., Ltd.
Yi Liu
Regulatory Affairs Specialist
4th and 5th Floor, Building Two, Hualian Industrial Zone,
Xinshi Community, Dalang Street
Shenzhen, Guangdong 518109
China

Re: K220448
Trade/Device Name: Disposable Non-invasive EEG Sensor
(Models: B-BIS-6A, B-BIS-6A-02, B-BIS-6A-01, B-BIS-6A-03, B-BIS-5A, B-BIS-5A-01, B-BIS-4A, B-BIS-4A-01, B-BIS-4P, B-BIS-4P-01, B-BIS-3A, B-BIS-3A-02, B-BIS-3A-01, B-BIS-3A-03, B-BIS-3AL, B-BIS-3AL-01, B-BIS-3AR, B-BIS-3AR-01)
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: Class II
Product Code: GXY
Dated: February 11, 2022
Received: February 16, 2022

Dear Yi 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,

Tushar Bansal -S

for Heather Dean, PhD
Assistant Director
THT5B3: Acute Injury Devices Team
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220448

Device Name
Disposable Non-invasive EEG Sensor (Device Models: B-BIS-6A, B-BIS-6A-02, B-BIS-6A-01, B-BIS-6A-03, B-BIS-5A, B-BIS-5A-01, B-BIS-4A, B-BIS-4A-01, B-BIS-4P, B-BIS-4P-01, B-BIS-3A, B-BIS-3A-02, B-BIS-3A-01, B-BIS-3A-03, B-BIS-3AL, B-BIS-3AL-01, B-BIS-3AR, B-BIS-3AR-01)

Indications for Use *(Describe)*
Disposable Non-invasive EEG Sensor is applied directly to the patient's skin to enable recordings of electrophysiological (such as EEG) signals.

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

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

Type of submission: Traditional

The assigned 510(k) number is: K220448

1. Submitter information

Manufacturer Name: Shenzhen Med-link Electronics Tech Co., Ltd.

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2. Correspondent

Yi Liu (Regulatory Affairs Specialist)

E-mail: user22@med-linket.com

3. Data of Preparation

11, Feb. 2022

4. Identification of the Device

Trade Name: Disposable Non-invasive EEG Sensor (Device Models: B-BIS-6A, B-BIS-6A-02, B-BIS-6A-01, B-BIS-6A-03, B-BIS-5A, B-BIS-5A-01, B-BIS-4A, B-BIS-4A-01, B-BIS-4P, B-BIS-4P-01, B-BIS-3A, B-BIS-3A-02, B-BIS-3A-01, B-BIS-3A-03, B-BIS-3AL, B-BIS-3AL-01, B-BIS-3AR, B-BIS-3AR-01)

Common Name: EEG Sensor

Classification Regulation: 21 CFR 882.1320

Regulation Name: Cutaneous electrode

Product Code: GXY

Class: II

Review Panel: Neurology

5. Identification of the Predicate Device

Table 1 Predicate Device Information

No.	Device Name	Common Name	Manufacturer	Classification and Product Code	Classification Regulation	510(k) Number
1	Covidien BIS Sensors (BIS Quatro Sensor, BIS Extend, BIS Pediatric Sensor, BIS Bilateral Sensor)	Electrode, Cutaneous Electrode	Medtronic Plc	Class II, GXY	21 CFR 882.1320	K143506
2	GE Entropy Sensor	Entropy Sensor	GE Healthcare	Class II, GXY	21 CFR 882.1320	K062580

6. Intended Use and Indications for Use of the Subject Device

Disposable Non-invasive EEG Sensor is applied directly to the patient's skin to enable recordings of electrophysiological (such as EEG) signals.

7. Device Description

Disposable Non-invasive EEG Sensor is a sensor assembly with pre-gelled electroencephalogram (EEG) electrodes. The Sensor is applied to the skin of the patient to record electrophysiological (such as EEG) signals. It is a low impedance, single patient use, non-sterile disposable electrode sensor that is designed for application to areas including forehead, temporal, above eyebrow and mastoid process. The Sensor is designed to provide ease of use and electrode placement accuracy. It is used in conjunction with a monitor with a n EEG module.

The sensor design is constructed using FPC (Flexible Printed Circuit Board) and medical foam. Place the foam plate and conductive gel on the FPC board. The bottom of the foam is covered with medical grade pressure sensitive adhesive for skin adhesion. A printed circuit board, which is part of the FPC board and printed with conductive silver/silver chloride, is pasted on the other side of the foam. The

flexible foam wrapped with conductive gel is used to contact the skin. When the flexible foam contacts the skin, the conductive gel will connect the skin with the FPC board to form a conductive bridge. The silver/silver chloride circuit provides signal continuity from each electrode to the monitor. The FPC board is attached to site like forehead and transmits EEG signals.

8. Comparison to the Predicate Device

Item	Proposed Device	Predicate Device #1	Predicate Device #2	Discussion
Trade name	Disposable Non-invasive EEG Sensor	Covidien BIS Sensors (BIS Quatro Sensor, BIS Extend, BIS Pediatric Sensor, BIS Bilateral Sensor)	GE Entropy Sensor	N/A
510(K) Submitter	Shenzhen Med-link Electronics Tech Co., Ltd.	Medtronic Plc	GE Healthcare	N/A
510(K) Number	K220448	K143506	K062580	N/A
Classification Regulation	21 CFR 882.1320	21 CFR 882.1320	21 CFR 882.1320	Same
Classification and Code	Class II, GXY	Class II, GXY	Class II, GXY	Same
Common Name	EEG sensor	Electrode, Cutaneous Electrode	Entropy sensor	N/A
Type of Use	Prescription	Prescription	Prescription	Same
Indications for Use	Disposable Non-invasive EEG Sensor is applied directly to the patient's skin to enable recordings of electrophysiological (such as EEG) signals.	The BIS Sensor is applied directly to the patient's skin to enable recordings of electrophysiological (such as EEG) signals.	The GE Entropy Sensor is intended to be used for adults with GE Entropy measurement devices to enable recording of physiological signals (such as EEG). To connect this sensor to the measurement device, use the GE Entropy Cable.	Same

Number of Electrodes	3/4/5/6	4/6	3	Different note 1
Application Site	Forehead/temporal/above eyebrow/mastoid process	Frontal/temporal area	Frontal/temporal area	Different note 2
Duration of Use	Maximum 24 hours	Not publicly available	Not publicly available	Different note 3
Usage	Disposable	Disposable	Disposable	Same
Applicable Population	Adult and pediatric	Adult and pediatric	Adults only	Same as Predicate Device #1
Operation Environment	Temperature: 5℃~40℃ Humidity:0～80%RH, non-condensing atmospheric pressure: 86kPa～106kPa	Not publicly available	Not publicly available	Different note 4
Storage Environment	Temperature: -10℃~40℃ Humidity:0～80% RH, non-condensing atmospheric pressure:86 kPa～106 kPa	Not publicly available	Not publicly available	Different note 4
Material	FPC, 3M Foam Tape (Silicone coated paper liner, Foam backing, Acrylate Adhesive), AgCl electrode, and conductive gel (a mixture of the following components:	Not publicly available	Not publicly available	Different note 3

	Water, Sodium Chloride, Gum Acacia, Guar Gum, and Xanthan Gum, Potassium Bitartrate , Glycerin, Methylparaben and Propylparaben.)			
Electrical Safety	Complies with ANSI/AAMI ES60601-1	Performed. Specific standard not specified in 510(k) Database.	Complies with EN 60601-1	Different note 5
Performance	Complies with ANSI/AAMI EC 12	Complies with ANSI/AAMI EC 12	Complies with ANSI/AAMI EC 12	Same
Biocompatibility	All the patient-contacting materials are evaluated by the biocompatibility standards ISO10993-5, ISO 10993-10.	Performed. Specific standard not specified in 510(k) Database.	All the patient-contacting materials are evaluated by the biocompatibility standards ISO10993-5, ISO 10993-10.	Same as Predicate Device #2
Sterilization	Non-sterile	Not publicly available	Non-sterile	Same as Predicate Device #2

Note 1
The number of 4/6 electrodes is the same as Predicate #1.
The number of 3 electrodes is the same as Predicate #2.
The number of 5 electrodes falls within the possible customizable number of electrodes of Predicate #1 (between 4 to 6 electrodes).
The difference of the number of electrodes of the proposed device does not affect its safe and effective usage in monitoring of EEG signals. The device has been tested in accordance with electrical safety and performance tests, and the tests passed. Thus, such a difference among the proposed device and the predicate devices does not affect substantial equivalence.

Note 2
Although the description of application sites of the proposed device are different from those of the predicate devices, the application sites are actually the same among three devices regarding frontal and temporal area. The actual use and application of the predicate devices on frontal area involve forehead and above eyebrow, with the description of the proposed device being more detailed. Regarding the additional application site of mastoid process that the proposed device specifies, it does not raise different questions of safety and effectiveness as the device meets safety and performance requirements.

Note 3
Although the usage time and material of the two predicate devices are not publicly available in the 510(k) Database, biocompatibility tests have been performed on the proposed device and the tests passed. Therefore, such a difference does not affect substantial equivalence among the proposed device and two predicate devices.

Note 4
The proposed device and the predicate devices all comply with electrical safety standards and performance standards. Therefore, absence of the information concerning Operation and Storage Environment of the two predicate devices does not raise questions of safety and effectiveness for the proposed device.

Note 5
Both the proposed device and the Predicate Device #2 performed electrical safety tests in accordance with 60601-1 standards.. Thus, the difference does not raise different questions of safety and effectiveness. The two devices are substantially equivalent regarding electrical safety.

9. Non-clinical Test

The safety and effectiveness of the subject device are demonstrated through testing following ANSI/AAMI ES60601-1 General requirements for basic safety and essential performance and ANSI/AAMI EC12: 2000/(R)2015 Disposable ECG Electrodes. The results of bench testing provides reasonable assurance that the proposed device has been designed and validated to assure conformance to the requirements for its indication for use. Package integrity and functional performance testing were completed on the subject device following Accelerated aging test to support the proposed shelf life.

10. Conclusion

Based on the comparison and analysis in this submission, it can be concluded that the Disposable Non-invasive EEG Sensor is substantially equivalent to the predicate devices.