May 6, 2022

Shenzhen Changke Connect Electronics Co., Ltd.
% Kevin Wang
Consultant
Chonconn Medical Device Consulting Co., Ltd.
Room 504, Block C, No. 1029 Nanhai Avenue, Nanshan District
Shenzhen, Guangdong 518067
China

Re: K213884
Trade/Device Name: Disposable EEG cable
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: December 10, 2021
Received: December 13, 2021

Dear Kevin Wang:

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,

Heather Dean, PhD
Assistant Director, 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)*
K213884

Device Name
Disposable EEG cable

Indications for Use *(Describe)*
The Disposable EEG cable is intended for non-invasive use with recording and monitoring equipment,(active and reference), of Electroencephalograph (EEG), electromyography (EMG), and Evoked Potentials (EP).

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.

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510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2022/03/27

1. Submission sponsor

Name: Shenzhen Changke Connect Electronics Co., Ltd.
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2. Submission correspondent

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Contact person: Kevin Wang
E-mail: kevin@chonconn.com
Tel: +86-755 33941160

3. Subject Device Information

Trade/Device Name	Disposable EEG cable
Common Name	Cutaneous electrodes
Regulatory Class	Class II
Classification	21CFR 882.1320 / Electrode, cutaneous / GXY
Submission type	Abbreviated 510(K)

4. Predicate Device

Dymedix Diagnostics, Inc., Disposable Gold Cup EEG Electrodes, K192564

5. Device Description

The Disposable EEG cable, which is cutaneous electrodes connected to lead wires, is non-invasive, single use electrodes intended to be used on normal, healthy, clean, intact skin for recording purposes.

In other words, the Disposable EEG cable is used in the acquisition of signals for the purpose of monitoring and recording Electroencephalograph(EEG), Electromyograph(EMG), and Evoked Potentials(EP). The Disposable EEG cable is delivered

non - sterile and are available in disposable version.

6. Intended use & Indication for use

The Disposable EEG cable is intended for non-invasive use with recording and monitoring equipment,(active and reference), of Electroencephalograph (EEG), electromyography (EMG), and Evoked Potentials (EP).

7. Comparison to the Predicate Device

Features	**Subject Device** Disposable EEG cable	**Predicate Device K192564** Disposable Gold Cup EEG Electrodes	**Comparison**
Applicant	Shenzhen Changke Connect Electronics Co., Ltd.	Dymedix Diagnostics, Inc.	/
Classification Regulation	21CFR 882. 1320	21CFR 882. 1320	Same
Classification and Code	Class II, GXY	Class II, GXY	Same
Indication for Use	The Disposable EEG cable is intended for non-invasive use with recording and monitoring equipment,(active and reference), of Electroencephalograph (EEG), electromyography (EMG), and Evoked Potentials (EP).	The Disposable Gold Cup EEG Electrodes are intended for non-invasive used with recording and monitoring equipment, (active and reference), of Electroencephalograph (EEG), Electromyography (EMG), and Evoked Potentials (EP)	Same
Anatomical sites	Scalp	Scalp	Same
Cup Diameter	10 mm	10 mm	Same
Lead wire Length(m)	3.05	1.0, 1.5, 2.0, 2.5	Different
Cup material	Gold Plated brass	Gold Plated brass	Same
Lead wire	PVC insulated tin plated copper	PVC insulated tin plated copper	Same

Features	**Subject Device** Disposable EEG cable	**Predicate Device** **K192564** Disposable Gold Cup EEG Electrodes	**Comparison**
Connectors	Molded touch proof 1.5 mm DIN connector (DIN 42-802)	Molded touch proof 1.5 mm DIN connector (DIN 42-802)	Same
Sterilization Method	Non Sterilization	Non Sterilization	Same
Patient populations	Adults and children	Adults and children	Same
Environment of Use	health care setting	health care setting	Same
OTC or Rx	Rx only	Rx only	Same
Method of Connection to the Patient	Conductive paste (provided by the user) provides electrode adhesive and conductivity. Additional adhesive tapes may be used	Conductive paste (provided by the user) provides electrode adhesive and conductivity. Additional adhesive tapes may be used	Same

In conclusion, the differences in technological characteristics do not raise new questions of safety and effectiveness.

8. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the Disposable EEG cable was conducted in accordance with the FDA Guidance for Industry and Food and Drug Administration Staff: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The biocompatibility testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

Non-clinical data

We performed electrical safety. The design of the Disposable EEG Electrodes 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 according to the <Cutaneous Electrodes for Recording Purposes - Performance Criteria for Safety and Performance Based Pathway > and ANSI AAMI EC12:2000/(R)2015 Disposable ECG electrodes.

Clinical data

Clinical testing is not required.

9. Conclusion

Performance testing and compliance with voluntary standards demonstrate that the proposed subject device is substantially equivalent to the predicate device.