March 19, 2024

Shenzhen Amydi-med Electrics Tech Co., Ltd.
Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K240668
Trade/Device Name: Amydi-med Disposable Non-invasive EEG electrodes
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: Class II
Product Code: GXY
Dated: August 21, 2023
Received: March 8, 2024

Dear Dave Yungvirt:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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, Acute Injury Devices Team
DHT5B: Division of Neuromodulation
and Rehabilitation 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240668

Device Name
Amydi-med Disposable Non-invasive EEG Sensor
(Models: AMD-DE-AF0001-1, AMD-DE-AF0002-l, AMD-DE-AF0003-l,AMD-DE-AF0004-l, AMD-DE-AF0005-1, AMD-DE-AF0006-1,AMD-DE-AF0007-l, AMD-DE-PF000l-1, AMD-DE-PF0004-l)

Indications for Use *(Describe)*
Amydi-med Disposable Non-invasive EEG Sensor is applied directly to an adults/pediatrics patient's skin to record physiological signals (e.g., the electroencephalogram, EEG) in the healthcare facility / hospital.

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.

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510(k) Summary

K240668

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

1. SUBMITTER

Shenzhen Amydi-med Electrics Tech Co., Ltd.

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Tel:	610-451-7988
Date Prepared:	March 14, 2024

2. DEVICE

Name of Device:	Amydi-med Disposable Non-invasive EEG Sensor (Models: AMD-DE-AF0001-1, AMD-DE-AF0002-1, AMD-DE-AF0003-1, AMD-DE-AF0004-1, AMD-DE-AF0005-1, AMD-DE-AF0006-1, AMD-DE-AF0007-1, AMD-DE-PF0001-1, AMD-DE-PF0004-1)
Common Name:	EEG Sensor
Classification Name:	Cutaneous electrode (21 CFR 882.1320)
Regulatory Class:	II
Product Code:	GXY

3. PREDICATE DEVICE

Name of Device:	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-BIS3AL, B-BIS-3AL-01, B-BIS-3AR, B-BIS-3AR-01)

510(k) Number: K220448

Submitter of Predicate Device: Shenzhen Med-link Electronics Tech Co., Ltd.

4. DEVICE DESCRIPTION

Amydi-med Disposable Non-invasive EEG Sensor is a low impedance, single patient use, disposable, non-sterile provided sensor that is designed for application to the sites including forehead, temporal, above eyebrow, and mastoid process. It is designed to provide ease of use and accurate electrode placement.

The main components of this sensor are the flexible PCB with electrodes, polyethylene base pad with medical grade pressure sensitive adhesive on its double sides, nylon plastic tine disks, polyurethane foam disks, aqueous gel（, and cable connector. Each sensor has three (3) to six (6) electrodes on the flexible PCB for different application sites.

5. INDICATIONS FOR USE

Amydi-med Disposable Non-invasive EEG Sensor is applied directly to an adults/pediatrics patient's skin to record physiological signals (e.g., the electroencephalogram, EEG) in the healthcare facility/hospital.

6. COMPARISON OF THE SUBJECT DEVICE WITH THE PREDICATE DEVICE

A comparison is performed between the subject device and predicate device. The result is summarized in Table 1.

Table 1 Comparison of the subject device and predicate device

Items	Subject Device	Predicate Device	Discussion

510(k) Number	K240668	K220448	N/A
510(K) Submitter	Shenzhen Amydi-med Electrics Tech Co., Ltd.	Shenzhen Med-link Electronics Tech Co., Ltd.	N/A
Classification / Regulation	Class II, 21 CFR 882.1320	Class II, 21 CFR 882.1320	Same
Product Code	GXY	GXY	Same
Common Name	EEG Sensor	EEG sensor	Same
Indications for Use	Amydi-med Disposable Non-invasive EEG Sensor is applied directly to an Adults/pediatrics patient's skin to record physiological signals (e.g., the electroencephalogram, EEG) in the healthcare facility/hospital.	Disposable Non-invasive EEG Sensor is applied directly to the patient’s skin to enable recordings of electrophysiological (such as EEG) signals.	Similar, Note 1
Environment of Use	Prescription	Prescription	Same
Target User	Neurologists	N/A	Similar, Note 1
Target Patient	Adults and pediatric	Adult and pediatric	Similar, Note 1
Application Sites	Forehead/temporal/above eyebrow/mastoid process	Forehead/temporal/above eyebrow/mastoid process	Same

Material	Flexible printed circuit board, electrodes screen-printed with cured Ag/AgCl and dielectric ink, polyethylene base pad with medical grade pressure sensitive adhesive, nylon plastic tine disks, polyurethane foam disks, aqueous gel (Water, Sodium Chloride, Gum Acacia, Guar Gum, Xanthan Gum, Potassium Bitartrate, Glycerin, Methylparaben and Propylparaben), and cable connector (polycarbonate).	Flexible printed circuit board, 3M Foam Tape (Silicone coated paper liner, Foam backing, Acrylate Adhesive), AgCl electrode, and conductive gel (a mixture of the following components: Water, Sodium Chloride, Gum Acacia, Guar Gum, and Xanthan Gum, Potassium Bitartrate, Glycerin, Methylparaben and Propylparaben.)	Note 2
Number of Electrodes	3/4/6	3/4/5/6	Note 3
Duration of Use	Maximum 24 hours	Maximum 24 hours	Same
Usage	Disposable	Disposable	Same
How to Be Supplied	Non-Sterile	Non-Sterile	Same
Biocompatibility Performance	ISO 10993-1 ISO 10993-5 ISO 10993-10	ISO 10993-1 ISO 10993-5 ISO 10993-10	Same
Electrical Safety	Not Tested	Complies with ANSI/AAMI	Note 4

		ES60601-1	
Electrical Performance	Comply with the ANSI/AAMI EC12: 2000 (R2015) Disposable ECG Electrodes.	Complies with ANSI/AAMI EC 12	Same
Adhesive Performance	IEC 60601-2-2 Ed. 6.0 b:2017 Medical Electrical Equipment – Part 2-2: Particular Requirements for The Basic Safety and Essential Performance of High Frequency Surgical Equipment and High Frequency Surgical Accessories, (a) Pull Test, (b) Conformability Test, (c) Fluid Tolerance Test.	Not publicly available	Note 5

Note 1. The expression is different, but the facts are the same.

Note 2. The materials and construction are the same. The composition of the materials is the same, though the brand of materials may be different. It will not raise new safety or effective issues. However, a Biocompatibility test was conducted and demonstrated the subject device's safety.

Note 3. The electrodes number of the subject device is covered by the predicate scope. No risks or safety issues will be raised.

Note 4. The requirement is not applied to Disposable Non-invasive EEG Electrodes as per the guidance document titled "Cutaneous Electrodes for Recording Purposes – Performance Criteria for Safety and Performance Based Pathway" (issued on August 14, 2020).

Note 5. The subject device passed one more test than the predicate. No safety or risks issue raised.

Summary: From the comparison table, the subject device has the same intended use, constructions, materials, and technological characteristics as the predicate device.

7. SAFETY AND PERFORMANCE DATA

According to the Non-invasive EEG Sensor specific guidance document titled "Cutaneous Electrodes for Recording Purposes – Performance Criteria for Safety and Performance Based Pathway" (issued on August 14, 2020), we conducted the following safety and electrical performance assessment using the specified FDA recognized standards (including methods and acceptable criteria).

i. Biocompatibility Performance

The biocompatibility evaluation for the subject device was conducted in accordance with ANSI/AAMI/ISO 10993-1: 2018 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process. The subject device is considered to be surface medical device contacting with intact skin and the contact duration is less than 24 hours. The biocompatibility evaluation endpoints are:

- **Cytotoxicity**
- **Irritation and skin sensitization**

The subject device successfully passed the above tests.

ii. Electrical Performance

Electrical testing was conducted on the subject device. The subject device complies with the ANSI/AAMI EC12: 2000 (R2015) Disposable ECG Electrodes.

iii. Adhesive Performance

The subject device has been designed and validated to satisfy the adhesive requirements per IEC 60601-2-2 Ed. 6.0 b:2017 Medical Electrical Equipment – Part 2-2: Particular Requirements for The Basic Safety and Essential Performance of High Frequency Surgical Equipment and High Frequency Surgical Accessories, (a) Pull Test, (b) Conformability Test, (c) Fluid Tolerance Test.

iv. Shelf Life

Shelf life testing were completed on the subject device following Accelerated aging test (60°C, 46 days) to support the proposed shelf life (1 year). The real time stability testing also demonstrates the shelf life of 1 year.

Summary: The subject device complies with the FDA recognized consensus standards for safety and performance criteria.

8. CONCLUSION

The subject device has the same intended use, constructions, materials, and technological characteristics as the predicate device. The subject device complies with the FDA recognized consensus standards for safety and performance criteria as required in the Non-invasive EEG Sensor specific guidance document titled "Cutaneous Electrodes for Recording Purposes – Performance Criteria for Safety and Performance Based Pathway" (issued on August 14, 2020).

Based on the safety and performance-based pathway, it can be concluded that the subject device is substantially equivalent to the predicate devices.