January 15, 2020

Dymedix Diagnostics, Inc.
Todd Eiken
Vice President of Product Development
5985 Rice Creek Parkway
Shoreview, Minnesota 55126

Re: K192564
Trade/Device Name: Disposable Gold Cup EEG Electrodes
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: September 12, 2019
Received: September 18, 2019

Dear Todd Eiken:

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, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192564

Device Name
Disposable Gold Cup EEG Electrodes

Indications for Use *(Describe)*

The Disposable Gold Cup EEG Electrodes are 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.

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5 510(k) Summary

Table 5.1 510(k) Summary (As required by section 21 CFR 807.92(c))	
Submitter:	Dymedix Diagnostics 5985 Rice Creek Parkway Shoreview, MN 55126 1-888-212-1100
Contact Person:	Todd Eiken Email: teiken@dymedix.com
Date Prepared	09-12-2019
Type of 510(k) Submission	Traditional
Reason for Submission	New Device
Multiple Devices	This is the only device in this submission
Trade Name:	Disposable Gold Cup EEG Electrodes
Common / Usual Name	Cutaneous electrodes
Classification Name	Electrode, cutaneous
Regulation Number	21 CFR §882.1320
Product Code	GXY, Cutaneous electrode
Establishment Registration:	3009351773
Predicate Devices:	DAEHAN: Disposable CUP Electrodes Technomed Europe: Cup electrodes
Device Description	The EEG electrodes are provided to the healthcare provider in either a set of 10 which are typically used for sleep studies or a set of 15 which are used for EEG monitoring. Each set of electrodes are the same length, however, sets can be ordered in lengths varying from 1.0 to 3.0 meters. Each electrode within a set has a different color to aid in placement.
Intended Use	The Disposable Gold Cup EEG Electrodes are intended for non-invasive use with recording and monitoring equipment, (active and reference), of Electroencephalograph (EEG), electromyography (EMG), and Evoked Potentials (EP)
Technology and Construction:	The technology and construction are similar to predicate in that we are utilizing
Environment of Use	The environments of use are similar –clinical settings where sleep studies may be performed.
Patient Population	The patient population is similar to the predicate namely, adults and children

The Disposable Gold Cup EEG Electrodes are based on technical features. A comparison with regard to these characteristics were found to be substantially equivalent to predicate devices.

Table 5.2

Device Comparison	**Proposed device**	**Predicate**	**Secondary Predicate**
K Number	K192564	K180232	K072016
Model	Disposable Gold cup EEG Electrodes	DAEHAN Disposable CUP Electrode	Cup Electrodes
Manufacturer	Dymedix Diagnostics, Inc.	Daehan Medical Systems Co., Ltd.	Technomed Europe
Classification	GXY Neurology 21 CFR 882.1320	GXY Neurology 21 CFR 882.1320	GXY Neurology 21 CFR 882.1320
Device Class	Class II	Class II	Class II
Indications for Use	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)	The CUP Electrodes are intended for non-invasive use with recording and monitoring equipment, (active and reference), of Electroencephalograph (EEG), electromyography (EMG), and Evoked Potentials (EP)	The Cup Electrodes are intended for non-invasive use with recording and monitoring equipment, (active and reference), of Electroencephalograph (EEG), electromyography (EMG), Evoked Potentials (EP)
Anatomical sites	Scalp	Scalp	Scalp
Cup Diameter	10 mm	10 mm	10 mm
Leadwire Length	1.0, 1.5, 2.0, 2.5	1.0, 1.5, 2.0, 2.5, 3.0M	1.0, 1.5, 2.0M
Cup material	Gold Plated brass	Ag/AgCl plated ABS	Gold Plated brass
Lead wire	PVC insulated tin plated copper	PVC insulated tin plated copper	PVC insulated tin plated copper
Connectors	Molded touch proof 1.5 mm DIN connector (DIN 42-802)	Molded touch proof 1.5 mm DIN connector (DIN 42-802)	Molded touch proof 1.5 mm DIN connector (DIN 42-802)
Sterilization Method	Non Sterilization	Non Sterilization	Non Sterilization
Target Population	Adults and children	Adults and children	Adults and children
Environment of Use	health care setting	health care setting	health care setting
OTC or Rx	Rx only	Rx only	Rx only
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	Conductive paste provides electrode adhesive and conductivity.

Table 5.2 compares the key features of the proposed Disposable Gold Cup EEG Electrodes with the identified predicates; K180232 – Daehan Disposable CUP Electrodes, and K072016 Technomed Europe Cutaneous Electrodes, which demonstrate that this proposed device can be found substantially equivalent.

In summary, one can conclude that substantial equivalence is met based upon the following:

Indications for Use –
The Indications for Use are identical. The electrodes can be used with Electroencephalograph (EEG), Electromyography (EMG), and Evoked Potentials (EP) monitoring equipment.

Technology and construction –
The technology and construction are similar to predicate in that we are utilizing an electrode of similar shape and size to collect and transmit signals through the connection wires to the monitoring device. The electrode materials are different from Daehan siver/silver chloride, compared to the gold plated cups used in the Dymedix electrodes which provide equal or better signal sensitivity. However, the Diposable Gold Cup EEG Electrodes are identical to Technomed Europe Gold Cup Electrodes.

Environment of Use –
The environments of use are similar –healthcare settings where monitoring studies may be performed.

Patient Population –
The patient population is similar to the predicate namely, adults and children.

Non-Clinical Testing Summary –

Biocompatibility
Biocompatibility testing has been performed to the applicable ISO 10993 standards for an external communicating device with a limited duration surface contact of use. The testing supports the patient contacting materials as non-cytotoxic, non-sensitizers, non-irritants, and non-toxic.

Bench testing
We have performed electrical performance testing to the ANSI/AAMI EC12:2000/(R)2015 standard which show the electrodes meet the standard.
Performance bench testing has verified the electrodes will perform adequately through the duration of use of the device. Mechanical bond testing, surface adhesive testing demonstrates the device integrity exceeds requirements for the intended use.

Conclusion
As discussed, the indications for use, patient population, environment of use, and performance are substantially equivalent.