November 1, 2018

Daehan Medical Systems Co., Ltd.
Da Pin Jeong
R&A Manager
250 Okgucheondong-Ro
Siheung-City, Gyeonggido
Republic of Korea 15084

Re: K180247
Trade/Device Name: DAEHAN Adhesive Surface Electrodes
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: August 6, 2018
Received: August 10, 2018

Dear Da Pin Jeong:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vivek J. Pinto -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological and Physical Medicine Devices
Office of Device Evaluation
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)*
K180247

Device Name
DAEHAN Adhesive Surface Electrodes

Indications for Use *(Describe)*
The DAEHAN Adhesive Surface Electrodes are intended for use with recording, monitoring and stimulation equipment for the purpose of stimulating/recording of biopotential signals. Electrodes are applied in the study of biopotentials such as Electroencephalograph (EEG), surface Electromyography (EMG), nerve conduction and Evoked potential signals (EP). Electrodes are non-invasive as they are applied to the, patient's skin using a self-adhesive solid-gel surface. The electrodes are non-sterile and for single patient use only.

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

[As required by 21 CFR 807.92]

1. Date Prepared [21 CFR 807.92(a)(a)]

Dec. 22. 2017

2. Submitter's Information [21 CFR 807.92(a)(1)]

- Name of Sponsor: Daehan Medical Systems Co., Ltd.
  - Address: 250 Okgucheondong-Ro, Siheung-City, Gyeonggido, 15084, Republic of Korea
- Contact Name: Da Pin Jeong / RA Manager
  - Telephone No.: +82-31-432-6275
  - Fax No.: +82-31-432-6276
  - Email Address: dpjeong@dmsleadwire.com

- Establishment Registration No.: 3002893037

- Name of Manufacturer: Same as Sponsor
  - Address: Same as Sponsor

3. Trade Name, Regulation Name, Classification [21 CFR 807.92(a)(2)]

- Trade Name: DAEHAN Adhesive Surface Electrodes
- Regulation Name: Cutaneous electrode
- Classification:

Classification Panel	Neurology
Classification Regulation	21 CFR 882.1320
Product Code	GXY
Device Class	II

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4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicate device within this submission is shown as follow;

- 510(k) Number: K073532
- Applicant: Technomed Europe
- Regulation Name: Cutaneous electrode
- Device Name: Disposable Adhesive Surface Electrodes

There are no significant differences between the DAEHAN Adhesive Surface Electrodes and the predicate device that would adversely affect the use of the product. It is substantially equivalent to these devices in design, function, and technical characteristics.

5. Description of the Device [21 CFR 807.92(a)(4)]

DAEHAN Adhesive Surface Electrodes are non-invasive. Cutaneous devices are used in the acquisition of signals for the purpose of stimulating, monitoring and recording Electroencephalograph (EEG), surface Electromyography (EMG) and Evoked Potentials (EP). The electrodes are designed for single-patient/multiple application use and are very flexible. Because of the adhesive nature of the gel, no securing material is required for fixating the electrode to the patient's skin. The electrodes with lead wire have a safety DIN 42802 connector, several lengths and color combinations.

6. Intended Use [21 CFR 807.92(a)(5)]

The Disposable Adhesive Surface Electrodes are intended for use with recording, monitoring and stimulation equipment for the purpose of stimulating/recording of biopotential signals. Electrodes are applied in the study of biopotentials such as Electroencephalograph (EEG), surface Electromyography (EMG), nerve conduction and Evoked potential signals (EP). Electrodes are non-invasive as they are applied to the, patient's skin using a self-adhesive solid-gel surface. The electrodes are non-sterile and for single patient use only.

7. Technological Characteristics [21 CFR 807.92(a)(6)]

The DAEHAN Adhesive Surface Electrodes are based on a technical feature comparison, the proposed device was found to be similar to predicate device with regard to design, function, and technical characteristics.

	Proposed Device	Predicate Device
K Number		K073532
Model	DAEHAN Adhesive Surface Electrodes	Disposable Adhesive Surface Electrodes
Manufacturer	Daehan Medical Systems Co., Ltd.	Technomed Europe
Device Class	Class II	Class II
Product code	GXY	GXY
Intended Use	The DAEHAN Adhesive Surface Electrodes are intended for use with recording, monitoring and stimulation equipment for the purpose of stimulating/recording of biopotential signals. Electrodes are applied in the study of biopotentials such as Electroencephalograph (EEG), surface Electromyography (EMG), nerve conduction and Evoked potential signals (EP). Electrodes are non-invasive as they are applied to the, patient's skin using a self-adhesive solid-gel surface. The electrodes are non-sterile and for single patient use only.	The Disposable Adhesive Surface Electrodes are intended for use with recording, monitoring and stimulation equipment for the purpose of stimulating/recording of biopotential signals. Electrodes are applied in the study of biopotentials such as Electroencephalograph (EEG), surface Electromyography (EMG), nerve conduction and Evoked potential signals (EP). Electrodes are non-invasive as they are applied to the, patient's skin using a self-adhesive solid-gel surface. The electrodes are non-sterile and for single patient use only.
Anatomical sites	Surface	Surface
Patch Area	20 and 40*50mm	20 and 40*50mm
Patient population	Adult	Adult
Conductive surface area	12.56㎠ and 20㎠	12.56㎠ and 20㎠
Lead Wire Length	1.0 and 2.0m	1.0 and 2.0m
Construction electrode	Three layers 1. Top sheet : Non woven Fabric 2. Conductive film: Carbon film coated with silver chloride 3. Conductive hydrogel	Three layers 1. Top sheet : Non woven Fabric 2. Conductive film: Carbon film coated with silver chloride 3. Conductive hydrogel
Lead wire material	PVC insulated tin plated with copper	PVC insulated tin plated with copper
PH	3.5~7.0	6.5+/-0.5
Impedance	<3KΩ	<3KΩ
Ingredients	Polymerization and cross linking of monomer	Polymerization and cross linking of monomer
Maximum duration of use	2hour	2hour
Connectors	DIN 42 802 1.5mm and Touch proof connector	DIN 42 802 1.5mm and Touch proof connector
Sterilization Method	Non Sterilization	Non Sterilization

Non-Clinical Test Summary:

1) Biocompatibility
   - ISO 10993-5: Biological evaluation of medical devices - Part 5: tests for in vitro cytotoxicity
   - ISO 10993-10: Biological evaluation of medical devices - Part 10: tests for irritation and skin sensitization

2) Performance Testing
   - Electrical property: AAMI/ANSI EC12 : Disposable ECG Electrodes

3) Shelf-life Testing
   - ASTM F1980-02, Standard guide for accelerated aging of sterile medical device package.

4) Basic Safety and Essential Performance
   - Electrical Safety: *AAMI/ANSI ES 60601-1:2005/(R)2012, CL 8.5.2.3 : Patient Leads*
   - *DAEHAN Adhesive Surface Electrodes were tested in accordance to the test requirements and test methods of subclause 8.5.2.3 of IEC 60601-1:2005 and are in conformance with AAMI/ANSI ES 60601-1:2005. The differences between IEC 60601-1:2005 and AAMI/ANSI ES 60601-1:2005 do not alter the safety and effectiveness of DAEHAN Adhesive Surface Electrodes.*

8. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92]

When compared to the predicate device (K073532), the DAEHAN Adhesive Surface Electrodes in this submission presented the substantial equivalence in terms of:

- Intended use
- Device design
- Components and materials
- Technological characteristics

9. Conclusion [21 CFR 807.92(b)(3)]

In according with the Federal Food & drug and cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification Daehan Medical Systems Co., Ltd., concludes that the DAEHAN Adhesive Surface Electrodes are substantially equivalent to predicate device as described herein.