DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 21, 2016

Daehan Medical Systems Co., Ltd.
Dong Cheul Kim
R&D Manager
250 Okgucheondong-ro
Siheung City, 15084 KR

Re: K161566
Trade/Device Name: DMS Disposable Subdermal Needle Electrodes
Regulation Number: 21 CFR 882.1350
Regulation Name: Needle Electrode
Regulatory Class: Class II
Product Code: GXZ,
Dated: November 15, 2016
Received: November 21, 2016

Dear Dong Cheul Kim:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161566

Device Name
DMS Disposable Subdermal Needle Electrodes

Indications for Use *(Describe)*
The DMS Disposable Subdermal Needle Electrodes are intended for use with recording, monitoring equipment for the recording of biopotential signals including electroencephalograph (EEG), electromyograph (EMG) and nerve potential signals, and are intended for stimulation/recording with stimulation/recording equipment for electromyograph (EMG) and nerve potential 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

[As required by 21 CFR 807.92]

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

Nov. 15, 2016

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, Republic of Korea, 15084
- Contact Name: Dong Cheul Kim / R&D Manager
  - Telephone No.: +82-31-432-6275
  - Fax No.: +82-31-432-6276
  - Email Address: dckim@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: DMS Disposable Subdermal Needle Electrodes
- Regulation Name: Needle Electrode
- Classification:

Classification Panel	Neurology
Classification Regulation	21 CFR 882.1350
Product Code	GXZ
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: K130136
- Applicant: Technomed Europe
- Regulation Name: Needle Electrode
- Device Name: Disposable Monopolar and Subdermal Needle Electrodes

There are no significant differences between the DMS Disposable Subdermal Needle 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)]

The DMS Disposable Subdermal Needle Electrodes are supplied sterile and intended for single use. This subdermal needle electrodes can be used to record the neurological and neurophysiological evoked potentials.

The connector is provided with touch-proof and cannot be connected to an AC outlet. This connector is designed for connecting the recording or monitoring equipment for the recording of biopotential signals including electroencephalograph (EEG), electromyograph (EMG) and nerve potential signals, and are intended for stimulation/recording with stimulation/recording equipment for electromyograph (EMG) and nerve potential signals.

The DMS Disposable Subdermal Needle Electrodes are supplied sterile.

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

The DMS Disposable Subdermal Needle Electrodes are intended for use with recording, monitoring equipment for the recording of biopotential signals including electroencephalograph (EEG), electromyograph (EMG) and nerve potential signals, and are intended for stimulation/recording with stimulation/recording equipment for electromyograph (EMG) and nerve potential signals.

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

The DMS Disposable Subdermal Needle Electrode are based on a technical feature comparison, the subject device was found to be similar to predicate device with regard to design, function, and technical characteristics.

	Proposed Device	Predicate Device
K Number	K161566	K130136
Model	DMS Disposable Subdermal Needle Electrode	Disposable Monopolar and Subdermal Needle Electrodes
Manufacturer	Daehan Medical Systems Co., Ltd.	Technomed Europe
Device Class	Class II	Class II
Product code	GXZ	GXZ and IKT
Intended Use	The DMS Disposable Subdermal Needle Electrodes are intended for use with recording, monitoring equipment for the recording of biopotential signals including electroencephalograph (EEG), electromyograph (EMG) and nerve potential signals, and are intended for stimulation/recording with stimulation/recording equipment for electromyograph (EMG) and nerve potential signals.	Needle Electrodes for Neurological purposes are intended for use with recording, monitoring equipment for the recording of biopotential signals including electroencephalograph (EEG), electromyograph (EMG) and nerve potential signals, and are intended for stimulation/recording with stimulation/recording equipment for electromyograph (EMG) and nerve potential signals.
Anatomical sites	Subdermal, nerve or muscle tissue	Subdermal, nerve or muscle tissue
Needle Diameter	0.41 mm	0.30 to 0.60 mm
Needle Length	12, 13, 14 and 16 mm	7 to 20 mm
Lead Wire Length	0.5, 1.0, 1.5, 2.0 and 2.5 m	1.0, 1.5 and 2.5 m
Needle material	Stainless steel	Stainless steel
Lead wire	PVC insulated tin plated with copper	PVC insulated tin plated with copper
Connectors	DIN 42 802 1.5mm and Touch proof connector	DIN 42 802 1.5mm and Touch proof connector
Sterilization Method	EO ethylene oxide	EO ethylene oxide
Sterility assurance level (SAL)	10^{-6}	10^{-6}

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

- Stiffness Test
- Breakage Test
- Bond Test
- Electrical Properties Test

3) Shelf-life Testing

- ASTM F1980-07:2011, Standard guide for accelerated aging of sterile barrier systems for medical devices

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

When compared to the predicate device (K130136), the DMS Disposable Subdermal Needle Electrode 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 DMS Disposable Subdermal Needle Electrodes are substantially equivalent to predicate device as described herein.