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510(k) Summary

[As required by 21 CFR 807.92]

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

Dec. 26. 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
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  - Fax No.: +82-31-432-6276
  - Email Address: drha@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 Disposable CUP Electrodes
- Regulation Name: Cutaneous Electrode
- Classification:

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

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

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

Primary predicate device

- 510(k) Number: K072016
- Applicant: Technomed Europe
- Regulation Name: Cutaneous Electrode
- Device Name: Disposable EEG Cup Electrode

Secondary predicate device

- 510(k) Number: K032278
- Applicant: Ambu, INC.
- Regulation Name: Cutaneous Electrode
- Device Name: Single Patient EEG/EP Cup Electrode

There are no significant differences between the DAEHAN Disposable CUP Electrodes and the predicate devices 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)]

A cutaneous electrode is an electrode that is applied directly to a patient's skin to record physiological signals. In other words cutaneous devices are used in the acquisition of signals for the purpose of monitoring and recording Electroencephalograph(EEG), Electromyograph(EMG), and Evoked Potentials(EP) and the electroencephalograph/evoked potentials reading is completely non-invasive procedure that can be applied to ***children and adult patients***. The electrodes are delivered non-sterile and are available in disposable version.

DAEHAN Disposable CUP electrodes are ***for single patient use only***. The electrodes have a disc manufactured of molded ABS, Ag/agcl plated. The disc is permanently adhered to a lead wire. The insulated lead wires terminate using a molded touch proof connector (DIN 42 802) for electrical safety.

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

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).

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

DAEHAN Disposable CUP 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	Primary Predicate Device	Secondary Predicate Device
K Number		K072016	K032278
Model	DAEHAN Disposable CUP Electrode	Disposable Cup electrodes	Single Patient EEG/EP Cup Electrode
Manufacturer	Daehan Medical Systems Co., Ltd.	Technomed Europe	Ambu, Inc
Device Class	Class II	Class II	Class II
Product code	GXY	GXY	GXY
Intended Use	The CUP electrodes are intended for non-invasive use with recording and monitoring equipment, (active and reference), of Electroencephalograph (EEG), electromyograph (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), electromyograph (EMG) and Evoked Potentials(EP).	The CUP electrodes are intended for use with recording, monitoring and stimulation equipment for the purpose of recording of biopotential signals for example: Electroencephalograph (EEG) and Nerve potentials signals. The electrodes are for single patient use only
Anatomical sites	Scalp	Scalp	Scalp
Cup	10mm	10mm	10mm

	Proposed Device	Primary Predicate Device	Secondary Predicate Device
Diameter			
Leadwire Length	1.0, 1.5, 2.0, 2.5, 3.0M	1.0, 1.5, 2.0M	1.0, 1.5, 2.0M
Cup material	Ag/AgCl plated ABS	Ag/AgCl plated ABS	Ag/AgCl plated ABS
Lead wire	PVC insulated tin plated copper	PVC insulated tin plated copper	PVC insulated tin plated copper
Connectors	DIN 42802 1.5mm and Touch proof connector	DIN 42802 1.5mm and Touch proof connector	DIN 42802 1.5mm and Touch proof connector
Sterilization Method	Non Sterilization	Non Sterilization	Non Sterilization

Non-Clinical Test Summary:

1) Biocompatibility

- Identical materials are used in legally marketed device

2) Performance Testing

- Bond Test
- Electrical Properties Test
- AAMI/ANSI EC12 : Disposable ECG Electrodes
- IEC 60601-1 Ed3.1 CL 8.5.2.3 : Patient Leads

3) Shelf-life Testing

- ASTM F1980-02, Standard Guide for Accelerated Aging of Sterile Medical Device Package.

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

When compared to the predicate devices (K072016 and K032278), DAEHAN Disposable CUP 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 DAEHAN Disposable CUP Electrodes are substantially equivalent to predicate devices as described herein.