May 7, 2026

Technomed Europe
Zara Grimshaw
Senior Regulatory Affairs Specialist
Wiebachstraat 25a
Limburg, 6466
Netherlands

Re: K254183
Trade/Device Name: MR Conditional Cup Electrodes
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: Class II
Product Code: GXY
Dated: April 8, 2026
Received: April 8, 2026

Dear Zara Grimshaw:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

Tushar Bansal, PhD
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K254183

Please provide the device trade name(s).

MR Conditional Cup Electrodes

Please provide your Indications for Use below.

The MR Conditional Cup Electrodes are intended for use in the recording of the Electroencephalogram (EEG), the Evoked Potentials (EP), or as a ground and reference in an EEG or EP recording. This device is non-sterile for Single Patient Use Only and may remain on the patient in an MRI or CT environment under specific conditions.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) SUMMARY
K254183
Technomed Europe's MR Conditional Cup Electrodes

1. Submitter Details

Technomed Europe,
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Phone: +31 (0) 43 408 6868
Contact Person: Zara Grimshaw, Senior Regulatory Affairs Specialist
Email: regulatorytechnomed@welcony.com
Date Prepared: 5th May 2026

2. Device

Name of Device: MR Conditional Cup Electrodes
Common Name: Cup Electrodes
Classification Name: Electrode, Cutaneous (21 CFR 882.1320)
Regulatory Class: II
Product Code: GXY

3. Predicate Device

Primary Predicate: Technomed's Cup Electrodes, K072016

2nd Predicate Device: Natus Manufacturing Ltd. Grass® MR Conditional/CT Cup Electrodes, Single and Array, K242346

4. Device Description

The MR Conditional Cup Electrodes consist of a small convex plastic (ABS) disc or cup (10mm in diameter), coated with a conductive material (silver/silver chloride (Ag/AgCl)) and attached to a conductive lead wire. The lead wire terminates at the other end with either a multi-pin connector (array variant) or a molded DIN 42802 touch proof connector (single variant). An extension cable is supplied to attach the electrode lead wire to the monitoring equipment. The extension cable is labeled as "MR Unsafe" and is not intended to be in the MRI environment.

The MR Conditional Cup Electrodes consist of non-ferromagnetic materials to minimize artifacts on both magnetic resonance imaging (MRI) and computational tomography (CT) imaging as well as to reduce safety risks like heating effects that can cause burns.

There are two product lines available:
1. The MR Conditional Single Connect System
2. The MR Conditional Array Connect System

The MR Conditional Single Connect System consists of two components: the MR Single Electrode (Single Electrode) and the MR Unsafe Extension Cable (Extension Cable). The MR Unsafe part of the product (Extension Cable), 1.0 to 2.5m long, is included to attach the electrode to monitoring equipment. The Extension Cable is clearly labeled with “MR Unsafe” symbols on both ends and is not intended to be used in the MR environment. This enables users to disconnect the MR Unsafe Extension Cables and leave the MR Conditional Single Electrodes (Single Electrodes) in place on the patient for MRI procedures. Up to 40 Single Electrodes can be used simultaneously on a patient.

The MR Conditional Array Connect System consists of two components: the MR Conditional Electrode Array (Electrode Array) and the MR Unsafe Extension Cable (Extension Cable). The MR Unsafe part of the product (Extension Cable), 1.0 to 2.5m long, is included to attach the Electrode Array to monitoring equipment. The Extension Cable is clearly labeled with “MR Unsafe” symbols on both ends and is not intended to be used in the MR environment. This enables users to quickly disconnect the MR Unsafe Extension Cable and leave the MR Conditional Electrode Array (Electrode Array) in place on the patient for MRI procedures. Each Electrode Array consists of up to 10 cups and up to 4 Electrode Arrays can be used simultaneously on a patient.

5. Indications for Use

The MRI/CT Cups are intended for use in the recording of the Electroencephalogram (EEG), the Evoked Potentials (EP), or as a ground and reference in an EEG or EP recording. This device is non-sterile for Single Patient Use Only and may remain on the patient in an MRI or CT environment under specific conditions.

6. Comparison of technological characteristics with the predicate device

Characteristic	Subject Device MRI/CT Cups	Primary Predicate (K072016)	2nd Predicate (K242346)	Similarities
Device Name	Cup Electrode	Cup Electrode	Cutaneous Electrode	Identical to predicates
Classification Code	GXY	GXY	GXY	Identical to predicates
Classification Name	Cutaneous, Electrode	Cutaneous, Electrode	Cutaneous, Electrode	Identical to predicates
Regulation Number	21 CFR 882.1320, Class II	21 CFR 882.1320, Class II	21 CFR 882.1320, Class II	Identical to predicates
Manufacturer	Technomed Europe	Technomed Europe	Natus Manufacturing Limited	Identical to primary predicate
Indications for Use	The MR Conditional Cup Electrodes are intended for use in Electroencephalography (EEG), the Evoked Potentials (EP), or as a ground and reference in EEG or EP recording. This device is non-sterile for Single Patient Use Only and may remain on the patient in an MRI or CT environment under specific conditions.	The Cup Electrodes are intended for non-invasive use with recording and monitoring equipment, (active and reference), of Electromyography (EMG), Electroencephalograph (EEG) and Evoked Potentials.	The Grass® MR Conditional/CT Cup Electrodes and Arrays are intended for use in the recording of the Electroencephalogram (EEG), the Evoked Potential (EP, or as a ground and reference in an EEG or EP recording. This device is non-sterile for Single Patient Use Only and may remain on the patient in an MRI or CT environment under specific conditions.	Identical to 2nd predicate. Similar to primary predicate.

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Target Population	Adult (age ≥ 21)	All patients	2 years and older	Equivalent to predicates – subject device has reduced target population
Where Used	Hospitals	Hospitals	Hospitals	Identical to predicates
Duration of Use	Prolonged (>24 hours but < 30 days)	Prolonged (>24 hours but < 30 days)	Prolonged (>24 hours but < 30 days)	Identical to predicates
Materials				
Electrode Material (patient contacting)	ABS 20% glass filled, AG/AgCl coated	ABS 20% glass filled, AG/AgCl coated	ABS 20% class filled, Ag/AgCl coated	Identical to predicates
Wire (non-patient contacting)	Conductive Carbon Fibre Cable, PVC coated	Tin plated copper lead wire	Carbon Conductive Cable, PVC coated	Equivalent in safety and effectiveness to 2nd predicate
Dimensions and Configurations				
Electrode Diameter	10mm	6mm or 10mm	10mm	Identical to predicates
Lead Wire Length	19.5cm (arrays) 28.2cm (singles)	Variety	27.0cm (arrays) 28.2cm (singles)	Singles identical to 2nd predicate. Arrays equivalent in safety and effectiveness
Extension Cable Length	1m to 2.5m	N/A	Unknown	Equivalent to 2nd predicate – does not impact safety and effectiveness
Configurations	Single and array	N/A	Single and array	Identical to 2nd predicate
Amount of arrays	1 to 4	N/A	1 to 4	Identical to 2nd predicate

Amount of electrodes	2 to 40 electrodes (up to 10 per array)	36 electrodes (adult population)	1 to 30 electrodes (5 to 9 lead wires per array)	Equivalent to predicates
Compatibility and Connections				
MR Conditions	MR Conditional in configurations of 2 to 40 electrodes, up to 10 per array. These electrodes can safely remain on a patient during an MR scan meeting the following conditions: - Static magnetic field of 1.5 and 3.0 - Max spatial field gradient 4,000 gauss/cm, - Whole-body averaged SAR of 2W/kg and whole head averaged SAR of 3.2W/kg, - Quadrature driven transmit body coil only	Not MR Conditional	MR Conditional in configurations of 1 to 30 electrodes, using 5 to 9 arrays. These electrodes can safely remain on a patient during an MR scan meeting the following conditions: - Static magnetic field of 1.5 and 3.0 Tesla - Maximum spatial field gradient of 3,000 gauss/cm [30T/m] - Maximum MR system reported whole-body averaged specific absorption rate (SAR) of 2 W/kg and whole-head averaged SAR of 3.2 W/kg	Equivalent to 2nd predicate – does not impact safety and effectiveness

	- 60 minutes of continuous scanning under normal operating mode		- Quadrature driven transmit body and head coil - Normal operating mode of SAR limits for 60 minutes of continuous RF	
Connector	Touch proof multipin connector (arrays) and Moulded touch proof connector (DIN 42802)	Moulded touch proof connector (DIN 42802)	Touch proof multipin connector	Identical to predicates
Other Information				
Max resistance	< 40 Ω (singles) < 30 Ω (arrays)	N/A	< 40 Ω (singles) <36.5 Ω (arrays)	Equivalent to 2nd predicate – does not impact safety and effectiveness
Impedance	< 500 Ω	< 2 kΩ	< 2 kΩ	Identical to predicates
Shelf Life	N/A	N/A	N/A	Identical to predicates
Sterility	Non-sterile	Non-sterile	Non-sterile	Identical to predicates
Single use	Yes	Single use and reusable variants	Yes	Identical to predicates

7. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Testing	Summary
Electrical Safety	The MR Conditional Cup Electrodes were verified for performance in accordance with IEC 60601-1, Clause 8.5.2.3 - *Medical Electrical Equipment – Part 1: General requirements for the basic safety and essential performance*.
Performance Testing - Bench	The MR Conditional Cup Electrodes successfully passed performance verification in accordance with internal requirements and specifications. The verification confirmed the device performed as intended and met all the defined acceptance criteria and did not raise any new concerns of safety and effectiveness. The following tests included: • **Visual Inspection** - Length and diameter of MR Conditional lead wire and extension cable - Length of shrink tubes - DIN42802 Guide pin measurements - Visual inspection cable, cup, shrink tube and finished product • **Mechanical Testing** - Wire tensile strength - Tensile strength cup to wire - Tensile strength DIN42802 to Wire - DIN42802 to 1.5mm pin extraction force (1x) - DIN42802 to 1.5mm pin extraction force after 30 mating/unmating cycles • **Electrical Testing** - AC impedance - Offset Voltage - Combined offset instability and internal noise - Bias Current Tolerance - Total electrical resistance of each separate electrode - Total end-to-end electrical resistance of each extension cable - Total electrical resistance of each electrode connected to extension cable

Biocompatibility Testing	The biocompatibility of the MR Conditional Cup Electrodes was conducted in accordance with ISO 10993-1:2018: *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*. The subject device is considered a surface device (skin) for a duration of >24 hours - ≤30 days. Biocompatibility of the subject device is confirmed.
MR Compatibility	The MR safety and performance of the MR Conditional Cup Electrodes was determined using the same test methodology as the predicate which included: • Worst case device configuration was established through feasibility testing • The worst-case configuration was tested to the applicable ASTM standards: - MR Image Artefact - Magnetically Induced Displacement Force - Magnetically Induced Torque • RF-Induced Heating and Gradient Induced Heating was tested according to ISO/TS 10974 The results of the MR safety and functional tests determined conditionality and labelling information for both 1.5T and 3.0T MR environments. Testing was carried out by an accredited MR testing laboratory and concluded that the MR Conditional Cup Electrodes demonstrated equivalence in terms of functionality, safety and effectiveness to the predicate device.

Animal and Clinical studies were not included as part of this submission.

8. Conclusion

The results of the performance testing described above demonstrate that the MR Conditional Cup Electrodes manufactured by Technomed Europe, are as safe and effective as the predicate devices and do not raise new concerns of safety and effectiveness, supporting a determination of substantial equivalence to the

predicate devices. The intended use and technology of the subject and predicate devices are equivalent.

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