August 29, 2024

Natus Manufacturing Limited
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K242346
Trade/Device Name: Grass® MR Conditional/CT Cup Electrodes, Single and Array
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: Class II
Product Code: GXY
Dated: August 7, 2024
Received: August 7, 2024

Dear Prithul Bom:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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,

Heather L. Dean -S

Heather Dean, PhD
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: 07/31/2026
*See PRA Statement below.*

Submission Number *(if known)*

K242346

Device Name

Grass® MR Conditional/CT Cup Electrodes ,Single
Grass® MR Conditional/CT Cup Electrodes, Array

Indications for Use *(Describe)*

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.
Intended Patient Population:2 Years and Older.

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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## *510K Summary*

**Preparation date:** August 7, 2024

**Applicant**:
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**Device:**
Proprietary Name**:** Grass® MR Conditional/CT Cup Electrodes ,Single, Grass® MR Conditional/CT Cup Electrodes, Array
Classification Name: Cutaneous Electrode
Regulation Number: 21 CFR 882.1320
Product code**:** GXY
Device Class: II,

**Predicate Device:**
510K Number: K172503
MR Conditional Cup Electrode, MR Conditional Webb Electrode

**Reference Device:**
510K Number: K171102
Ives MR Conditional Cup Electrode

**Indications for Use**:
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.

**Device Description:**

## Overview: Grass® MR Conditional/CT Cup Electrodes

Grass® MR Conditional/CT Cup Electrodes are for surface monitoring EEG, electromyogenic and physiologic data signals commonly recorded on the chest, extremities, head and faces of patients. Grass® MR Conditional/CT Array Cup Electrodes are also used in electrocardiography, evoked potentials, and polysomnography. The Grass® MR Conditional/CT Array Cup Electrodes are MR conditional/CT. The included extension cables are MR/CT Unsafe.

## Operating Principle of the Grass® MR Conditional/CT Cup Electrodes

The Operating Principle and technological characteristics of the Grass MR Conditional Cup Electrodes are identical to the predicate device (K171102), with a few dimensional and material modifications that have been assessed to be equivalent to the predicate and therefore do not affect the fundamental scientific technology, safety, or effectiveness of the device (reference Substantial Equivalence of Technological Characteristics table, below). The test methods were identical to those used to assess the predicate device.

## System Setup Overview

Use a cotton tip applicator to apply a small amount of skin prep gel such as NuPrep® to the site of the electrode application scrubbing gently.

Fill the electrode cup with a conductive paste or gel such as Ten20®. Do not overfill the cup. Excessive amount of paste or gel can result in asymmetric signals.

Fix the cup to the patient with a small amount of pressure.

Use a small pre-cut gauze square or piece of paper tape to help secure the cup electrode to the application site.

Check that clear, strong signals are being transmitted.

When ready to remove the electrode cup, carefully remove gauze square or tape and remove any gel or paste with soap and water.

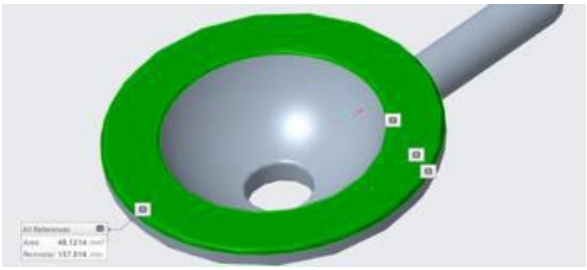
After use, discard the electrodes.

**Device-patient interaction Accessories List:**

Cup Electrodes are applied on the patient's skin, including but not limited to, the head (scalp). Only the cup portion of the Grass MR/CT Conditional Electrodes, which has contact with the patient (see the portion highlighted in green in Figure 2), is categorized as B - Prolonged (>24

hours but <30 days). When accounting that up to 30 electrodes are used on the scalp of the patient at one time, the total contacting surface area corresponds to 14.4 cm².

Figure 1. Patient contacting part of the cups.



The rest of the device (everything except the cups) is either contacting the hair of the patient or has very brief (transient contact) with the patient and caretaker during placement.

Grass® MR Conditional/CT Cup Electrodes does not have any accessory.

**Intended User:**

Grass® MR Conditional/CT Cup Electrodes and Arrays are for professional use only and should be used in compliance with accepted industry standards.

**Intended Patient Population:**

2 Years and Older.

**Clinical Benefits:**

Facilitates obtaining the recording of an EEG study to detect any irregularities indicative of various brain disorders.

## Comparison to Predicate Device

| Feature | Subject Device<br><br>Grass® MR Conditional/CT Cup Electrodes | PREDICATE DEVICE<br><br>Rythmlink (K172503) | PREDICATE DEVICE<br><br>IVES Electrode (K171102) | Similarities |
|---|---|---|---|---|
| Intended Use/ Indications for Use | The MR Conditional/CT cup electrodes are intended for use in the recording of the Electroencephalogr am (EEG), the evoked potential (EP), or as a ground and reference in an EEG or EP recording.<br>This device is non-sterile for Single Patient Use Only and may remain on the patient in an MRI/CT environment under specific conditions. | The MR Conditional Cup Electrodes are intended for use in the recording of the Electroencephalogr am (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 environment under specific conditions. | The Ives MR Conditional Cup Electrodes are intended for use in the general recording and monitoring of the electroencephalograph y (EEG), evoked potential (EP) as well as ground and reference related to the EEG and EP recording.<br><br>The Cup Electrodes are intended to be left in place during MR imaging at 1.5T and 3T as well as during CT scanning. The extension cable must be disconnected from the Ives MR Conditional Cup Electrodes before scanning and MUST remain disconnected throughout the entire MR scan. EEG or EP should not be recorded throughout the entire the CT and MR imaging. | Same as predicate |
| Configuratio ns | Single and Array | Single and Array | Not Available | Same as predicate |

| Feature | Subject Device<br><br>Grass® MR Conditional/CT Cup Electrodes | PREDICATE DEVICE<br><br>Rythmlink (K172503) | PREDICATE DEVICE<br><br>IVES Electrode (K171102) | Similarities |
|---|---|---|---|---|
| MR Conditions | Non-clinical testing has demonstrated that the MR Conditional /CT Cup and Electrodes Array is MR Conditional in configurations of 1 to 30 electrodes, using 5 to 9 arrays. These electrodes can safely remain on a patient during a MR scan meeting the following conditions:<br>• Static magnetic field of 1.5 or 3.0<br>• Tesla Maximum spatial field gradient of 3,000 gauss/cm [30 T/m]<br>• 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.<br>• Quadrature driven transmit body and head coil.<br>• Normal operating mode SAR limits for 60 minutes of continuous RF | Non-clinical testing has demonstrated that the MR Conditional Cup Electrode array is MR Conditional in configurations of 2 to 40 electrodes, using 1 to 4 arrays. These electrodes can safely remain on a patient during an MR scan meeting the following conditions:<br>• Static magnetic field of 1.5 and 3.0 Tesla<br>• Maximum spatial field gradient of 4,000 gauss/cm [40 T/m]<br>• 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<br>• Quadrature driven transmit body coil only<br>• Maximum active scan time of 15 Minutes | MR Conditional and can safely remain on the patient during an MR scan under the following conditions:<br>• Static magnetic fields strength of 1.5 T and 3.0 T<br>• Maximum spatial gradient magnetic fields of 2,000 gauss/cm (20T/m) or less<br>• Transmit body and head coil, quadrature driven<br>• 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<br>• The extension cable must be disconnected from the Ives MR Conditional Cup Electrodes before scanning and must remain disconnected throughout the entire MR scan. | Same as predicate |

| Feature | Subject Device<br><br>Grass® MR Conditional/CT Cup Electrodes | PREDICATE DEVICE<br><br>Rythmlink (K172503) | PREDICATE DEVICE<br><br>IVES Electrode (K171102) | Similarities |
|---|---|---|---|---|
| Electrode Material | ABS 20% glass filled, Ag/AgCl coated | ABS 20% glass filled, Ag/AgCl coated | ABS molded plastic with Ag- Ag/Cl | Same as predicate |
| Electrode Diameter | 10mm | 10mm | 10 mm | Same as predicate |
| Wire | Carbon conductive cable, PVC coated | Conductive cable, PVC coated | Tinseled copper with silver coat with | Equivalent in safety and effectiveness |
| Electrode Cable Length Singles (Lead wire) | 282 mm | 28.2 cm (282mm) | Not Available | Similar to predicate |
| Electrode Cable Length Arrays<br><br>(Lead wire) | 270 mm | 18 cm | Tested at 15.24 cm (152.4 mm) to 27.94 cm (279.4 mm) as well as marketed | Equivalent in safety and effectiveness; Non-clinical MRI testing and all performance testing was performed on 270mm length arrays. Increase in length doesn't affect safety and effectivity of the device. |
| Connector | Touch proof multipin connector(s) | Touch proof multipin connector(s) | Touch proof multipin connector(s) | Same as predicate |

| Feature | Subject Device<br><br>Grass® MR Conditional/CT Cup Electrodes | PREDICATE DEVICE<br><br>Rythmlink (K172503) | PREDICATE DEVICE<br><br>IVES Electrode (K171102) | Similarities |
|---|---|---|---|---|
| Max resistance Singles | < 40Ω | Not available | Not available | Meets the performance criteria per FDA Guidance for Cutaneous Electrodes for Recording Purposes – Performance Criteria for Safety and Performance Based Pathway. |
| Max resistance Arrays | < 36.5Ω | Not available | Not available | Meets the performance criteria per FDA Guidance for Cutaneous Electrodes for Recording Purposes – Performance Criteria for Safety and Performance Based Pathway. |
| Impedance | 2 kOhms Maximum (Average Value of 10-Hz impedance for 12<br><br>electrode pairs), 3 kOhms Maximum (Individual pair impedance) | Not available | Not available | Meets the performance criteria per FDA Guidance for Cutaneous Electrodes for Recording Purposes – Performance Criteria for Safety and Performance Based Pathway. |

The Grass® MR Conditional/CT Cup Electrodes and the predicate device are equivalent in features and technical characteristics. There are no major differences that alter the intended use or raise new issues of safety or effectiveness.

**Brief Summary of Performance Testing**

***Electrical Safety***

The Grass® MR Conditional/CT Cup Electrodes was verified for performance in accordance with the following standard:

- *IEC 60601-1 Edition 3.2 2020-08 Clause 8.5.2.3 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*

***Packaging and Handling Verification***

The packaged Natus Grass® MR Conditional/CT Cup Electrodes components have successfully passed packaging and handling verification per ASTM D4169

***Performance Testing – Bench Verification & Validation***

The Natus Grass® MR Conditional/CT Cup Electrodes has successfully passed performance verification and validation in accordance with internal requirements and specifications at the system level.

The Bench testing verification and validation was performed to confirm device meets the functional and performance characteristics.

Additionally, Natus Grass® MR Conditional/CT have been tested internally and met defined acceptance criteria. The tests included:

- Functional Test
- Mechanical design Test
- Electrical Safety Test
- Biocompatibility Test
- Packaging
- FDA Guidance for Cutaneous Electrodes for Recording Purposes – Performance Criteria for Safety and Performance Based Pathway

Results indicate that the Grass® MR Conditional/CT Cup Electrodes system complies with its predetermined specifications and the applicable standards.

**Non-Clinical Testing:**

The MR safety and performance equivalency of the Natus Grass® MR Conditional/CT Electrodes were determined using the same test methodology as the predicate device, summarized below:

- Worst-case device configuration was established through feasibility testing.
- The established worst-case configuration of the finished device was tested to the applicable ASTM standards:

- RF-Induced Heating
- MR Image Artifact
- Magnetically Induced Torque
- Magnetically Induced Displacement Force

The results of these MR safety and functional tests determined the MR conditionality and device labelling information for both 1.5 T and 3.0 T MR environments.

All MR testing was performed by an accredited MR testing laboratory on behalf of Natus Medicals. In summary, the non-clinical testing concluded that the Natus Grass® MR Conditional/CT Electrodes demonstrated equivalent functionality, safety, and effectiveness as the predicate device.

**Clinical Tests:**

No Clinical Tests were conducted as referenced in 21 CFR 807.92(b)(2).

**Conclusions**

The substantial equivalence of the Grass® MR Conditional/CT Cup Electrodes with the predicate device(s) was demonstrated by testing in compliance with the Design Control process. The intended use and technology of the Grass® MR Conditional/CT Cup Electrodes is similar to that of the predicate device(s). Verification and Validation were performed to ensure no new questions of safety or effectiveness are raised. The results of these activities demonstrate that the Grass® MR Conditional/CT Cup Electrodes is as safe, as effective, and performs as well as or better than the predicate device.