July 14, 2026

Ambu A/S
% Sanjay Parikh
Senior Director, QA/RA
Ambu, Inc.
6721 Columbia Gateway Dr., Suite 200
Columbia, Maryland 21046

Re: K260578
Trade/Device Name: Ambu® NeurolineTM Cup MRI/CT
(Models 72704/21US, 72704/23US, 72704/25US, 72704/27US);
Ambu® NeurolineTM Cup MRI/CT-set
(Models 72704/21-1010US, 72704/23-1010US, 72704/25-1010US, 72704/27-1010US);
Ambu® NeurolineTM Cup MRI/CT-mini set
(Models 72704/21-0301US, 72704/23-0301US, 72704/25-0301US, 72704/27-0301US)
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: February 20, 2026
Received: February 20, 2026

Dear Sanjay Parikh:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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

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.

510(k) Number *(if known)*
K260578

Device Name
Ambu® NeurolineTM Cup MRI/CT (Models 72704/21US, 72704/23US, 72704/25US, 72704/27US);
Ambu® NeurolineTM Cup MRI/CT-set (Models 72704/21-1010US, 72704/23-1010US, 72704/25-1010US, 72704/27-1010US);
Ambu® NeurolineTM Cup MRI/CT-mini set (Models 72704/21-0301US, 72704/23-0301US, 72704/25-0301US, 72704/27-0301US)

Indications for Use *(Describe)*

The Ambu® Neuroline™ Cup MRI/CT is intended to obtain and transmit electroencephalography (EEG) or evoked potential (EP) signals to the compatible Ambu harness, from where the signals can be transmitted to a monitoring and recording device.

The Ambu® Neuroline™ Cup MRI/CT is intended to be disconnected from all harness cables and left in place on the patient during Magnetic Resonance (MR) imaging and Computerized Tomography (CT) scanning.

The Ambu® Neuroline™ Cup MRI/CT is indicated when there is a need for neurophysiological examination of the brain.

The Ambu® Neuroline™ Cup MRI/CT can be used for adults and pediatrics (from 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.

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510(k) Summary – K260578

Date Prepared	14-July-2026
Company Name and Address	Ambu A/S Baltorpbakken 13 DK-2750 Ballerup Denmark Tel: +45 7225 2000
Prepared and Submitted by:	Lenka Vaculčiaková Regulatory Affairs Professional Tel: +45 7225 2837 Email: leva@ambu.com
Official Contact:	Sanjay Parikh Senior Director, QA/RA Address: Ambu Inc. 6721 Columbia Gateway Drive, Suite 200 Columbia, Maryland 21046 Tel: +1 443 831 9844 Email: sap@ambu.com
Applicant Device Trade Name:	Ambu® Neuroline™ Cup MRI/CT (Models 72704/21US, 72704/23US, 72704/25US, 72704/27US) Ambu® Neuroline™ Cup MRI/CT-set (Models 72704/21-1010US, 72704/23-1010US, 72704/25-1010US, 72704/27-1010US) Ambu® Neuroline™ Cup MRI/CT-mini set (Models 72704/21-0301US, 72704/23-0301US, 72704/25-0301US, 72704/27-0301US)
Classification Name :	21 CFR § 882.1320, Cutaneous electrode
FDA Product Code:	GXY
Regulatory Class:	II
Type of Submission:	Traditional
Predicate Device Trade Name:	Grass® MR Conditional/CT Cup Electrodes, Single and Array
510(k) Number:	K242346
Manufacturer Name:	Natus Manufacturing Limited
Reference Device	No reference devices were used in this submission.

1. Device Description

Ambu® Neuroline™ Cup MRI/CT is a non-sterile, single-use and Magnetic Resonance (MR) Conditional set of electroencephalography (EEG) electrode arrays, intended to obtain and transmit EEG or evoked potential signals from the brain. The Ambu® Neuroline™ Cup MRI/CT can be left in place on the patient during MR imaging (MRI) and Computerized Tomography (CT) scanning. The Ambu® Neuroline™ Cup MRI/CT supports various EEG montages of 21, 23, 25 and 27 sensor cups.

2. Intended Use / Indications for Use

The Ambu® Neuroline™ Cup MRI/CT is intended to obtain and transmit electroencephalography (EEG) or evoked potential (EP) signals to the compatible Ambu harness, from where the signals can be transmitted to a monitoring and recording device.

The Ambu® Neuroline™ Cup MRI/CT is intended to be disconnected from all harness cables and left in place on the patient during Magnetic Resonance (MR) imaging and Computerized Tomography (CT) scanning.

The Ambu® Neuroline™ Cup MRI/CT is indicated when there is a need for neurophysiological examination of the brain.

The Ambu® Neuroline™ Cup MRI/CT can be used for adults and pediatrics (from 2 years and older).

3. Comparison of Indications for use and Technological Characteristics with the Predicate Device

	Applicant Ambu® Neuroline™ Cup MRI/CT	**Predicate Device** Grass® MR Conditional/CT Cup Electrodes, Array	**Substantial equivalence assessment**
	REGULATORY INFORMATION		
Manufacturer	Ambu A/S	Natus Manufacturing Limited	N/A
Device trade name and model no.	Ambu® Neuroline™ Cup MRI/CT	Grass® MR Conditional/CT Cup Electrodes, Array	N/A
510(k) number	K251583 - application	K242346	N/A
Product code	GXY		Same
Regulation description	Cutaneous electrode		Same
Regulation number	882.1320		Same
Device Classification	Class II		Same
	USE OF PRODUCT		

	Applicant Ambu® Neuroline™ Cup MRI/CT	**Predicate Device** Grass® MR Conditional/CT Cup Electrodes, Array	**Substantial equivalence assessment**
Intended use/Indications for use	The Ambu® Neuroline™ Cup MRI/CT is intended to obtain and transmit electroencephalography (EEG) or evoked potential (EP) signals to the compatible Ambu harness, from where the signals can be transmitted to a monitoring and recording device. The Ambu® Neuroline™ Cup MRI/CT is intended to be disconnected from all harness cables and left in place on the patient during Magnetic Resonance (MR) imaging and Computerized Tomography (CT) scanning. The Ambu® Neuroline™ Cup MRI/CT is indicated when there is a need for neurophysiological examination of the brain. The Ambu® Neuroline™ Cup MRI/CT can be used for adults and pediatrics (from 2 years and older).	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.	Equivalent to predicate (Ref. Note 1)
Device configuration	Array		Same
Rx Only	Yes		Same
MR designation	MR conditional		Same
MR conditions	A person with Ambu® Neuroline™ Cup MRI/CT attached (arranged in a configuration of maximum of 3 Sensor Arrays with max. 9 Sensor Lead Wires each, i.e., a total of 27 Sensor Lead) may be safely scanned under the following conditions: - Static magnetic field of 1.5 or 3.0 Tesla - Maximum spatial field gradient of 3,000 gauss/cm [30 T/m]	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: - Static magnetic field of 1.5 or 3.0 Tesla - Maximum spatial field gradient of 3,000 gauss/cm [30 T/m]	Equivalent to predicate device (Ref. note 2)

	Applicant Ambu® Neuroline™ Cup MRI/CT	**Predicate Device** Grass® MR Conditional/CT Cup Electrodes, Array	**Substantial equivalence assessment**
	- MR system reported whole-body averaged specific absorption rate [SAR] ≤ 2 W/kg and whole-head averaged SAR ≤ 3.2 W/kg - Quadrature driven / Circularly Polarized (CP) RF coils: Use only scanner's transmit body coil and a receive-only head coil. Other types (e.g. surface array coils) are acceptable if they are receive-only. - Normal operating mode SAR limits for 60 minutes of continuous RF for body and head/neck landmarks	- 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. - Quadrature driven transmit body and head coil. - Normal operating mode SAR limits for 60 minutes of continuous RF	
CT imaging in presence of the device	Yes		Same
	TECHNOLOGICAL CHARACTERISTICS and SPECIFICATIONS		
Electrode Material	20% carbon filled polycarbonate (PC) acrylonitrile butadiene styrene (ABS) coated with Ag/AgCl	ABS 20% glass filled, Ag/AgCl coated	Equivalent to predicate device (Ref. note 3)
Electrode Diameter	10 mm		Same
Wire	Carbon conductor, Thermoplastic elastomer (TPE) insulation	Carbon conductive cable, polyvinyl chloride (PVC) coated	Equivalent to predicate device (Ref. note 4)
Electrode Cable Length	320 mm	270 mm	Equivalent to predicate device (Ref. note 5)
Connector	Touch proof multipin connector(s)		Same
Delivered sterile	No		Same
Single use	Single Use	Single Patient Use Only	Equivalent to predicate device (Ref. note 6)
	GENERAL PERFORMANCE		
Resistance	< 100 Ω	< 36.5 Ω	Equivalent to predicate device (Ref. note 7)

	Applicant Ambu® Neuroline™ Cup MRI/CT	**Predicate Device** Grass® MR Conditional/CT Cup Electrodes, Array	**Substantial equivalence assessment**
Impedance	≤ 2 kΩ @10Hz for a sensor pair	2 kOhms Maximum (Average Value of 10 Hz impedance for 12 electrode pairs), 3 kOhms Maximum (Individual pair impedance)	Equivalent to predicate device (Ref. note 8)

Note 1. The applicant and predicate devices are MR conditional and intended for EEG and EP recording and monitoring. Both devices are equally intended to be disconnected and detached from the harness cables during MRI or CT scanning. The applicant and predicate devices are considered equivalent in their intended use.

Note 2. Both, the applicant device and the predicate device support standard EEG montage configurations. MR conditional designation of both devices is supported for identical MR systems. Both predicate and subject devices are to be used with quadrature driven transmit body coil, which is widely used in clinical settings for MRI scanning.

In addition to the transmit body coil, the predicate device supports the use in combination with quadrature driven transmit head coil. Therefore, the applicant device specifies the exact type of head coil to be receive-only in the MRI safety information section of the Instructions for Use. The applicant device specifies MRI scanner landmark positions for a set of landmarks typically associated with neurophysiological examinations of the brain as per simulations.

Based on the RF heating simulation results, the use of other types of receive-only surface array coils is supported, which differs from the predicate. RF heating simulation results show worst case RF induced heating occurring around landmark 10 cm (upper neck region) and then reduces significantly towards landmark position 30 (sternum), as the patients head (and hence the subject device) is subjected to a rapidly decreasing E-field when the patients head protrudes out of the scanner bore. Thus, it is concluded that the applicant device can be used with any types of surface array receive-only coils, since their effect on local E-field relevant to RF induced heating of the subject device is minimal. In addition, the receive-only coils don't produce RF energy by themselves, meaning that the subject device can be used with any type of receive-only coil, at any landmark position.

The MRI scan duration limits follow *FDA guidance: Testing and Labelling Medical Devices for Safety in the Magnetic Resonance (MR) Environment* and were determined by simulations. The scan durations of both the predicate and subject devices are in a range where obtaining MRI scans in a clinical setting is feasible. Because the final calculated tissue temperature rise (3.8°C) is below the 4°C safety threshold for thermally non-sensitive tissue, a continuous 60-minute scan duration with the above MR scan parameter limits is acceptable.

Given the above information, the differences are considered negligible and do not raise different questions of safety and effectiveness.

Note 3. The applicant device as well as the predicate device use the silver/silver chloride (Ag/AgCl) layer on the cup serving as the conductive interface making direct contact with the patient. This conducting silver/silver chloride layer ensures accurate signal transmission during use and is commonly found in surface electrodes used for biosignal monitoring. The cup material underneath the conducting layer is different compared to the predicate device. The 20% carbon filled PC ABS is chosen to enhance the signal transmission, while the material is tested to withstand necessary mechanical properties needed to

fulfill the intended use. Sensor underwent biological evaluation testing. The use of 20% carbon filled PC ABS instead of ABS 20% glass filled as the cup material underneath the conducting layer, raises no additional questions of safety or effectiveness.

Note 4. The applicant device as well as the predicate device use carbon as the lead wire conductor material. The insulation is different with TPE being used compared to PVC used in the predicate device. The TPE lead wire insulation is tested to perform similar insulating properties as PVC insulation, and the TPE insulation material withstands the necessary mechanical and electrical properties needed to fulfil the intended use. Sensor lead wire insulation underwent biological evaluation testing. The use of TPE as an insulation does not raise additional question of safety or effectiveness.

Note 5. The electrode cable length of the applicant device is longer than the predicate device. The performance of the subject device (e.g. Impedance) is not adversely impacted by the increased electrode cable length, which is supported by verification test ensuring compliance with ANSI AAMI EC12, Section 4.2.2.1.

The longer lead wire length does not adversely impact the safety of the device under intended use. Mechanical and electrical testing have verified the safety of the device under intended use conditions. The effect of longer lead wire length on the product's MR Conditional labelling has been considered. The product follows *FDA guidance: Testing and Labelling Medical Devices for Safety in the Magnetic Resonance (MR) Environment* and the product safety (where the device is disconnected and unpowered while still mounted on a patient undergoing MRI scanning) is supported by testing in compliance with ASTM F2052, ASTM F2213 and ASTM F2119-07. Additional support is provided by simulations of the product using a validated model.

Note 6. Restriction to single use designation of the applicant device in comparison to the single-patient use designation of the predicate device is considered a risk-reducing change. At the same time, the applicant device as well as the predicate carry 'Do not re-use' symbol in labelling. The applicant device contains a warning stating 'Do not reuse, clean, or disinfect the sensor array as it is a single-use device. Failure to comply can cause patient injury leading to infections or cause device malfunction.' Considering the content of the warning and cautions, both devices are equivalent in their uses.

Note 7. The applicant device as well as the predicate devices meet the performance criteria per FDA Guidance for Cutaneous Electrodes for Recording Purposes – Performance Criteria for Safety and Performance Based Pathway, supported by testing.

Note 8. Both devices are compliant with ANSI AAMI EC12, Section 4.2.2.1. The predicate device requires 1) that the average impedance of 12 electrodes pairs must be no greater than 2 kΩ and 2) that the impedance of each pair must be no greater than 3 kΩ. In comparison, the Ambu® Neuroline™ Cup MRI/CT has tightened this requirement, so that the impedance of each pair must be no greater than 2 kΩ. This ensures that the average of 12 electrode pairs will also be no greater than 2 kΩ.

4. Non-Clinical Tests Summary

The following tests were performed to verify/validate the design and evaluate the performance of the Ambu® Neuroline™ Cup MRI/CT. Where relevant, the testing was conducted on Ambu® Neuroline™ Cup MRI/CT in conjunction with Ambu® Neuroline™ EEG Harness.

Verification tests include:

- Strength of Sensor
- Electrical and Mechanical test (inspired by ANSI/AAMI EC53)

- Electrical testing (ANSI/AAMI EC12)
- Electrical safety (IEC 60601-1)
- MR Conditional Testing (ASTM F2052-21, ASTM F2213-17 and ASTM F2119-07 (2013))
- Sensor Radiopacity (ASTM F640-23)
- Product Packaging and Labelling

Transportation study according to ASTM D4169-22.
Stability study to document shelf life after accelerated aging according to ASTM F1980.

Biocompatibility according to ISO 10993-1 including tests for:
- Physical and/or chemical information (ISO 10993-18)
- Cytotoxicity (ISO 10993-5)
- Irritation (ISO 10993-23)
- Sensitization (ISO 10993-10)

In all instances, the Ambu® Neuroline™ Cup MRI/CT performed as expected and met the test specifications set.

5. Conclusions

All included bench tests, which have been designed to evaluate substantial equivalence as well as the product's conformity to established quality and performance measures, have been successfully conducted, documented, and have passed the predefined acceptance criteria. As a result, it is concluded that the Ambu® Neuroline™ Cup MRI/CT meets its predefined specifications and performs as intended in conjunction with Ambu® Neuroline™ EEG Harness.

Based on the intended use, technological characteristics and the non-clinical performance tests, the subject device is as safe, as effective, and performs at least as safely and effectively as the predicate device.