June 7, 2024

NORAS MRI products GmbH
% Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct
Naples, Florida 34114

Re: K241069
Trade/Device Name: iLoop Interventional Coil 0.55T
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: MOS
Dated: April 11, 2024
Received: April 22, 2024

Dear Daniel Kamm:

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,

Daniel M. Krainak, Ph.D.
Assistant Director
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of Radiological Health
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K241069

Device Name
iLoop Interventional Coil 0.55T

Indications for Use *(Describe)*

The intended use of the iLoop Interventional Coil 0.55T is, in conjunction with a Magnetic Resonance Scanner, the MR examination of the human body. Used in a magnetic resonance tomograph, the iLoop Interventional Coil 0.55T is intended to produce transversal, sagittal, coronal and oblique images of the internal structures of the body. This device may be used for interventional procedures.

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 K241069

NORAS MRI Products GmbH
Leibnizstrasse 4
Hoechberg
Germany 97204
Telephone: 49-931-299270
E-Mail: mri@noras.de
www.noras.de

Date Prepared: May 30, 2024

A) SUBMITTED BY: NORAS MRI Products GmbH, Inc

B) CONTACT: Manuel Noras, Chief Executive Officer

C) Device Identification

Trade/Device Names:	iLoop Interventional Coil 0.55T
Regulation Number:	21 CFR 892.1000
Regulation Name:	Magnetic resonance diagnostic device
Regulatory Class:	II
Product Code:	MOS

D) Predicate Device:

Predicate Device:	K203443
Manufacturer:	Siemens Medical Solutions USA, Inc.
Trade/Device Name:	MAGNETOM (Including Flex Loop Large local coil)
Regulation Number:	21 CFR 892.1000
Regulation Name:	Magnetic resonance diagnostic device
Regulatory Class:	II
Product Code:	MOS

E) DEVICE DESCRIPTION: The iLoop Interventional Coil 0.55T is a 1-channel receiver coil that can be used for MR imaging before, during and after MR-guided interventions with a Siemens MRI System with field strength 0.55T. The iLoop Interventional Coil 0.55T can also be used as a standard diagnostic coil for diagnostic examination of the human body. The iLoop Interventional Coil 0.55T is a coil that can be used on many different regions of the body. Used in conjunction with a sterile, self-adhesive OP-drape, the coil enables the workflow for MR-guided interventions

F) INDICATIONS FOR USE The intended use of the iLoop Interventional Coil 0.55T is, in conjunction with a Magnetic Resonance Scanner, the MR examination of the human body. Used in a magnetic resonance tomograph, the iLoop Interventional Coil 0.55T is intended to produce transversal, sagittal, coronal and oblique images of the internal structures of the body. This device may be used for interventional procedures.

G) SUBSTANTIAL EQUIVALENCE: The predicate Flex Loop Large Coil from Siemens has a very similar geometry to the device under evaluation. It is also a one-channel receiving coil and has the same diameter of the inner conductor. The absence of directly attached cable to the plug highlights the difference in design. Both devices are compatible with different MRI scanners and used on different field strengths but perform identical functions using similar designs and materials.

H) SUBSTANTIAL EQUIVALENCE COMPARISON AND DISCUSSION

	K203443 MAGNETOM Vida, MAGNETOM Sola, MAGNETOM Lumina, MAGNETOM Altea with syngo MR XA31A (Includes Flex Loop Large local coil)	**iLoop Interventional Coil 0.55T**	**Comparison**
Indication for Use	Your MAGNETOM system is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra, and that displays the internal structure and/or function of the head, body, or extremities. Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, contrast agents may be used. These images and/or spectra and the physical parameters derived from the images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.	The intended use of the iLoop Interventional Coil 0.55T is, in conjunction with a Magnetic Resonance Scanner, the MR examination of the human body. Used in a magnetic resonance tomograph, the iLoop Interventional Coil 0.55T is intended to produce transversal, sagittal, coronal and oblique images of the internal structures of the body. This device may be used for interventional procedures.	Functionally the same. The new iLoop represents a subset of the predicate indications.
Appearance	Flex Loop Large Coil 	iLoop Coil 	SIMILAR
Construction/Use	• one-channel RF receive-only surface loop coil • the diameter of the inner conductor is 19 cm • it does not have a 1000 mm cable attached to the plug • used with a field strength of 1.5T and 3T • used on the Magnetom Altea, Magnetom Avanto and Magnetom Sola systems	• one-channel RF receive-only surface loop coil • the diameter of the inner conductor is 19 cm • a 1000 mm cable is directly attached to the plug • used with a field strength of 0.55T • used on the MAGNETOM Free.Max system	Similar function but for use on different systems.
Dimensions	19 cm opening	19 cm opening	SAME
Function	Employs a coil system which serves solely as a receiving coil for the reception of high frequency signals from the hydrogen -(^{1}-H) nuclei. The hydrogen nuclei are induced into precession by the transmitting coil of the MRI device.	Identical mode of operation	SAME

	K203443 MAGNETOM Vida, MAGNETOM Sola, MAGNETOM Lumina, MAGNETOM Altea with syngo MR XA31A (Includes Flex Loop Large local coil)	iLoop Interventional Coil 0.55T	Comparison
Biocompatibility	Patient contact parts tested to ISO 10993	SAME	SAME

I) SUMMARY OF PERFORMANCE TESTING.

This device was tested in accordance with the FDA special controls guidance: *Magnetic Resonance (MR) Receive-only Coil – Performance Criteria for Safety and Performance Based Pathway, Guidance for Industry and Food and Drug Administration Staff Document issued on December 11, 2020*. We conducted these tests successfully as called for in the guidance:

- Image Signal to Noise (SNR)
- Image Uniformity
- Surface heating
- Acquired Image Quality
- Decoupling circuit inspection
- EMC – Immunity, electrostatic discharge, Methodology: FDA currently recognized version of IEC 60601-1-2, FDA Recognition (Performed within the test report for IEC 60601-2-33:2022)
- General electrical/mechanical safety: IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020 (FDA Recognition 19-49

Patient contact materials were subjected to ISO 10993 tests for: Cytoxicity, Irritation, and sensitization.
Testing was done according to IEC60601-2-33 Edition 4.0 2022-08 Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis, FDA Recognition 12-347
Usability testing was performed in accordance with: IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability, FDA Recognition 5-132.
In addition, testing was performed in accordance with IEC standard: IEC60601-1-6 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability, FDA Recognition 5-132. A detailed risk analysis was also performed.

J) CLINICAL TESTING: Not required.

K) CONCLUSION: In all material aspects, the iLoop interventional coil 0.55T model of MR coil performed equivalently to the predicate device, had similar construction methods, and has not raised any new issues of safety or effectiveness. The predicate MAGNETOM (Including Flex Loop Large local coil) has a similar intended use as the predicate, thus rendering the new model of MRI coil substantially equivalent to the predicate.