Neoscan Solution GmbH
Roell Stefan
Executive Director
Joseph-von-Fraunhofer-Str. 6
Magdeburg, 39106
GERMANY

July 22, 2024

Re: K231133
Trade/Device Name: neo315
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH
Dated: June 18, 2024
Received: June 18, 2024

Dear Roell Stefan:

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,

Lora D. Weidner, 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.

Submission Number *(if known)*

K231133

Device Name

neo315

Indications for Use *(Describe)*

The neo315 is a magnetic resonance diagnostic device which is intended for general diagnostic use to present images which reflect the spatial distribution and/or magnetic resonance spectra which reflect frequency and distribution of nuclei exhibiting nuclear magnetic resonance. Other physical parameters derived from the images and/or spectra may also be produced.

The device includes hydrogen-1 (proton) imaging, hydrogen-1 spectroscopy, and chemical shift imaging (preserving simultaneous frequency and spatial information). The intended group of patients for the neo315 can be found in the pediatric environment. The exclusion of patients is determined by the dimensions of the patient bed and excludes patients that exceed a 120 cm length and a diameter of 26 cm.The weight of the patient shall not exceed 18 kg.

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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510(k) #: K231133

510(k) Summary

Prepared on: 2024-06-18

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Neoscan Solutions GmbH
Applicant Address	Joseph-von-Fraunhofer-Str. 6 Magdeburg 39106 Germany
Applicant Contact Telephone	+491728444690
Applicant Contact	Mr. Roell Stefan
Applicant Contact Email	roell@neoscan-solutions.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	neo315
Common Name	Magnetic resonance diagnostic device
Classification Name	System, Nuclear Magnetic Resonance Imaging
Regulation Number	892.1000
Product Code	LNH

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K123938	Siemens MAGNETOM Avanto syngo MR B19A	LNH

Device Description Summary

21 CFR 807.92(a)(4)

The neo315 is a conductively cooled 1.5T whole body magnetic resonance diagnostic device (MRDD) which generates images which reflect the spatial distribution and/or magnetic resonance spectra which reflect frequency and distribution of nuclei exhibiting nuclear magnetic resonance. Its intended group of patients for the neo315 can be found in the pediatric environment. The neo315 consists of the Field Generating Unit (FGU), two technical cabinets (consoles) and gets operated via the operating software ScanUI.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The neo315 is a magnetic resonance diagnostic device which is intended for general diagnostic use to present images which reflect the spatial distribution and/or magnetic resonance spectra which reflect frequency and distribution of nuclei exhibiting nuclear magnetic resonance. Other physical
parameters derived from the images and/or spectra may also be produced.

The device includes hydrogen-1 (proton) imaging, hydrogen-1 spectroscopy, and chemical shift imaging (preserving simultaneous frequency and spatial information). The intended group of patients for the neo315 can be found in the pediatric environment. The exclusion of patients is determined by the dimensions of the patient bed and excludes patients that exceed a 120 cm length and a diameter of 26 cm.The weight of the patient shall not exceed 18 kg.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The major difference between neo315 and the predicate device is a 30 cm patient bore, allowing only to image the pediatric patients. The reduced size of the patient tunnel allows however neo315 to be more compact, bear less weight, and occupy only a quarter of the footprint of the predicate device.

Neo315 has the same major indications for use as the predicate device: both devices produce transverse, sagittal, coronal and oblique cross-sectional images and/or spectra, and that display the the internal structure and/or function of the head, body, or extremities.

The above described differences do not constitute a new intended use nor a safety and effectiveness issue.

Technological Comparison 21 CFR 807.92(a)(6)

The selected equivalent device is directly comparable with the medical device under evaluation. The clinical, technical, and biological characteristics are similar or even identical with the neo315. In terms of clinical and biological characteristics, the two devices do not differ at all. All the aspects investigated are the same here. Only the technical characteristics have minor differences, which result mainly from the different size of the devices. The discussed aspects have no influence on the clinical performance or safety of the device. The neo315 is as secure as an MAGNETOM Avanto in terms of safety and can be used for diagnostics with the same clinical performance as an MAGNETOM Avanto.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The neo315 is claimed to comply with the following applicable FDA recognized standards:

NEMA MS-1-2008 (R2020) - Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Imaging

NEMA MS 2-2008 (R2020) - Determination of Two-Dimensional Geometric Distortion in Diagnostic Magnetic Resonance Images

NEMA MS 3-2008 (R2020) - Determination of Image Uniformity in Diagnostic Magnetic Resonance Images

NEMA MS 4-2010 - Acoustic Noise Measurement Procedure for Diagnosing Magnetic Resonance Imaging Devices

NEMA MS 5-2018 - Determination of Slice Thickness in Diagnostic Magnetic Resonance Imaging

NEMA MS 8-2016 - Characterization of the Specific Absorption Rate (SAR) for Magnetic Resonance Imaging Systems

IEC 60601-1-2 Edition 4.1, 2020-09 CONSOLIDATED Version - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance

IEC 60601-2-33 Ed. 3.2 b:2015 - Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of Magnetic Resonance Equipment for Medical Diagnostic

IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION - Medical Device Software - Software life cycle processes

IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION

ISO 10993-1 Fifth edition 2018-08 - Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

IEC 62366-1 Edition 1.0 2015-02 - Medical devices - Part 1: Application of usability engineering to medical devices

ISO 14971 Third Edition 2019-12 - Medical devices - Application of risk management to medical devices

The performance testing results demonstrate the safety and performance as expected. Therefore, the neo315 is substantially equivalent to the legally marketed predicate device.