February 8, 2024

Neuro42, Inc.
Abhita Batra
Chief Strategy Officer
2 Bryant Street, Suite 240
San Francisco, California 94105

Re: K232644
Trade/Device Name: neuro42 MRI System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH, MOS
Dated: August 30, 2023
Received: December 26, 2023

Dear Abhita Batra:

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.

Submission Number *(if known)*

K232644

Device Name

neuro42 MRI System

Indications for Use *(Describe)*

The neuro42 Magnetic Resonance Imaging System is a bedside magnetic resonance imaging device for producing images that display the internal structure of the head where full diagnostic examination is not clinically practical. When interpreted by a trained physician, the images can provide diagnostically useful information.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary K232644

Submitter Information

Submitter name: neuro42, Inc
Address: 2 Bryant St. Suite 240, San Francisco, CA 94105
Telephone Number: (480) 241-3211
Contact Person: Abhita Batra
Date of Preparation: August 29, 2023

Name of Device

Trade/Device name: neuro42 MRI System
Model Number/Name: n42-m

Indications for Use

The neuro42 Magnetic Resonance Imaging System is a bedside magnetic resonance imaging device for producing images that display the internal structure of the head where full diagnostic examination is not clinically practical. When interpreted by a trained physician, the images can provide diagnostically useful information.

Device Description

neuro42 MRI System is a low-field MR system intended to be used for neuroimaging. The neuro42 Magnetic Resonance Imaging System is a bedside magnetic resonance imaging device intended to be used for producing images that display the internal structure of the head. The device is a low-field magnetic resonance system and includes a movable magnet cart on wheels connected to a separate electronic cabinet on wheels. The system utilizes a permanent Halbach magnet array and does not require any external shielding.

Classification Name

	Regulation Number	Product Code
System, Nuclear Magnetic Resonance Imaging	892.1000	LNH
Coil, Magnetic Resonance, Specialty	892.1000	MOS

Predicate Device

The predicate device for neuro42 MRI system is:

Trade Name	Common Name	Class	Product Code	Manufacturer	K-number
Lucy Point-of-Care MRI System	MRI System	II	LNH, MOS	Hyperfine Research, Inc.	K192002

Comparison of Specifications

Comparison of Specifications	Lucy Point-of Care Magnetic Resonance Imaging device (K192002)	neuro42 MRI System
Intended Use/Indications for Use	The Lucy Point-of-Care Magnetic Resonance Imaging Device is a bedside magnetic resonance imaging device for producing images that display the internal structure of the head where full diagnostic examination is not clinically practical. When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis.	The neuro42 Magnetic Resonance Imaging is a bedside magnetic resonance imaging device for producing images that display the internal structure of the head where full diagnostic examination is not clinically practical. When interpreted by a trained physician, the images can provide diagnostically useful information.
Patient Population	Adult and pediatric patients (above 2 years old)	Adult patients (above 18 years old)
Anatomical Sites	Head	Head
Environment of Use	At the point of care in medical facilities including emergency rooms, critical care units, hospital or rehabilitation rooms.	At the point of care in medical facilities including intensive care (ICU), emergency and urgent care, stroke centers or outpatient and ambulatory care.
Energy Used and/or Delivered	Magnetic Resonance	Magnetic Resonance
Human Factors	Lucy is designed similar to other commercially available MRI Systems and therefore is familiar and easy to use for the user. Furthermore, the device contains a user-friendly software interface through which the user may easily access all device functions	The neuro42 MRI System is designed similar to other commercially available MRI Systems and therefore is familiar and easy to use for the user. Furthermore, the device contains a user-friendly software interface through which the user may easily access all device functions
Magnet:		
Physical Dimensions	83.5 cm x 63.0 cm x 65.2 cm	MRI Cart: 72 cm x 74 cm x 120 cm

		Electronic Cabinet: 60 cm x 100 cm x 152 cm
Bore Opening	61 cm x 31.5 cm	33.5 cm × 28.5 cm
Weight	320 kg	MRI Cart: 200 kg Electronic Cabinet: 380 kg
Field Strength	64 mT permanent magnet	70 mT permanent magnet
Gradient:		
Strength	16 mT/m	13.07 mT/m
Rise Time	0.5 ms	0.3 ms
Slew Rate	28 T/m/s	43.57 T/m/s
Computer:		
Display	User supplied tablet	Touch screen monitor on electronic panel
RF Coils:	1 Head Coil	2 Head Coils
Coil Type	TX/RX	TX/RX
Coil Geometry	Form-fitting	Form-fitting
Inner Dimensions (mm)	20.5 cm x 24 cm	n42-cm: 19 cm × 21 cm n42-cl: 21 cm × 24 cm
Coil Design	Linear Volume	Linear Volume
Target Population	Adult and pediatric patients (above 2 years old)	Adult patients (above 18 years old)
Patient bed dimensions	n/a	n/a
Patient Weight Capacity	200 kg	n/a
Operation Temperature	18-25 °C	15-25 °C
Warm Up Time	3 minutes	< 3 minutes
Temperature Control	No	No
Humidity Control	No	No

Technological Characteristics

There are some differences in technological characteristics between the subject device and the predicate device, including different hardware configuration and software. However, the technology meets the same intended use and performs the same actions.

Summary of Testing and Performance Data

neuro42 MRI System has been evaluated to demonstrate substantial equivalence related to medical electrical equipment, risk management, software verification and validation, and image quality and has been found to conform to the following medical device safety standards:

- IEC 60601-1:2005 (3rd Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 + A2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-2-33:2022 (4th Edition) Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis
- IEC 60601-1-2:2014/AMD1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 62304 Edition 1.1 2015-06 Consolidated Version
- AIM 7351731 Rev. 3.00 (2021-06-04) – Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers
- 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 for Magnetic Resonance Imaging Systems
- NEMA MS 12-2016 Quantification and Mapping of Geometric Distortion for Special Applications
- NEMA MS 14-2019 Characterization of Radiofrequency (RF) Coil Heating in Magnetic Resonance Imaging Systems
- Other Standards
- ISO 10993-1:2018 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process.

No clinical trials were performed. Sample clinical images were provided to support substantial equivalence.

Conclusion

Substantial equivalence comparison including intended use, function, specifications, and

technological characteristics of the neuro42 MRI System with the predicate device demonstrates that neuro42 MRI System is substantially equivalent to the listed predicate.