February 21, 2023

Time Medical Limited
% Nick Tse
VP, Regulatory and Quality Systems
Flat/Rm 301, 3/F 20E, 20 Science Park East Avenue
Hong Kong Science Park
Shatin, Hong Kong, HKSAR
CHINA

Re: K222259
Trade/Device Name: NEONA 1.5T MRI System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH
Dated: January 12, 2023
Received: January 20, 2023

Dear Nick Tse:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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
Magnetic Resonance and Nuclear Medicine Team
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)*
K222259

Device Name
NEONA 1.5T MRI System

Indications for Use *(Describe)*
NEONA 1.5T MRI system is indicated for use as a magnetic resonance diagnostic device (MRDD) which produces transverse, sagittal, coronal and oblique cross-sectional images, and those display the internal structure and/or function of the head, body, or extremities. Depending on the region of interest, contrast agents may be used. These images when interpreted by trained physician yield information that may assist medical diagnosis.

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 OF SAFETY AND EFFECTIVENESS

This 510(k) Summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date of Submission:	
Sponsor:	Time Medical Limited Unit 301, 20E, Science Park East Ave, Hong Kong Science Park, Shatin, New Territories, Hong Kong, China Contact Person: Nick Tse – VP, Regulatory and Quality System Telephone number: +852 21561711 (ext. 119) Fax.: +852 2156 0908
Correspondent:	Time Medical Limited Unit 301, 20E, Science Park East Ave, Hong Kong Science Park, Shatin, New Territories, Hong Kong, China Contact Person: Nick Tse – VP, Regulatory and Quality System Telephone number: +852 21561711 (ext. 119) Fax.: +852 2156 0908
Filing Device:	NEONA 1.5T MRI System
Classification Name:	System. Nuclear Magnetic Resonance Imaging
Regulatory Description:	Magnetic Resonance Diagnostic Device (MRDD)
Classification Class	Class II / LNH / 21 CFR 892. 1000
Intended Use:	NEONA 1.5T MRI system is indicated for use as a magnetic resonance diagnostic device (MRDD) which produces transverse, sagittal, coronal and oblique cross-sectional images, and those display the internal structure and/or function of the head, body, or extremities. Depending on the region of interest, contrast agents may be used. These images when interpreted by trained physician yield information that may assist medical diagnosis.
Device Description:	The NEONA 1.5T MRI System is a 1.5T superconducting magnet MRI system which produces transverse, sagittal, coronal and oblique cross-sectional images, and those display the internal structure and/or function of the head, body, or extremities. It is composed of Magnet, Magnet Enclosure, Patient Table, Gradient Coil, Transmission Coil, Receiver Coil, Client PC, and Imaging Cabinet. The system software, Prodiva, a Windows-based software, is an interactive program with user friendly interface. The device is conformed to IEC and DICOM standards.

General Comparison to Predicate Device:

Comparison Element	Filing Device:	Predicate Device:
510(k) Number	N.A.	K183621
Model	15000-02	15000-01
Device Name	NEONA 1.5T MRI System	EMMA 1.5T MRI System
Applicant	Time Medical Limited	Time Medical Limited
Classification Name	System, Nuclear Magnetic Resonance Imaging	System, Nuclear Magnetic Resonance Imaging
Product Code	LNH	LNH
Regulation Number	21 CFR 892.1000	
Panel	Radiology	
Class	Class II	
Indications for Use	NEONA 1.5T MRI system is indicated for use as a magnetic resonance diagnostic device (MRDD) which produces transverse, sagittal, coronal and oblique cross-sectional images, and those display the internal structure and/or function of the head, body, or extremities. Depending on the region of interest, contrast agents may be used. These images when interpreted by trained physician yield information that may assist medical diagnosis.	The EMMA 1.5T MRI System is indicated for use as a magnetic resonance diagnostic device (MRDD) which produces transverse, sagittal, coronal and oblique cross-sectional images, and those display the internal structure and/or function of the head, body, or extremities. Depending on the region of interest, contrast agents may be used. These images when interpreted by trained physician yield information that may assist medical diagnosis.

The filing device has the same US FDA classification information including classification name, product code, regulation number, panel, and class with the predicate device.

The filing device has the same major indications for use as the predicate device: the device produces transverse, sagittal, coronal and oblique cross-sectional images, and those display the internal structure and/or function of the head, body, or extremities. Depending on the region of interest, contrast agents may be administrated according to physician's instructions. These images when interpreted by trained physician yield information that may assist medical diagnosis.

The minor differences in indications for use do not constitute any safety and effectiveness issue, as indicated in the performance data provided.

Technological Characteristics	NEONA 1.5T MRI system is based on the principle that certain atomic nuclei present in the human body, when placed in a strong magnetic field and excited by a radio frequency signal at the precession frequency, will emit a relaxation signal. The emitted relaxation signals are acquired by signal receiving coils and are analyzed by the system. Human-interpretable images are reconstructed by and stored in the computer and displayed on the screen. The principal components of NEONA 1.5T MRI system includes • Superconducting magnet with corresponding cooling devices • Gradient system • RF transmission and receive system • Cooling system for different components of the system • Patient table and support components • Spectrometer • Server/Client PC and application software The superconducting magnet is made of coils of superconducting wires and is cooled to and maintained at low temperature. When energized, current flows continuously inside the superconducting wires as a closed loop; thus producing a constant magnetic field. This has the same major technological characteristics as the predicate device. The gradient system consists of a gradient coil and the gradient amplifier. The gradient coil produces varying linear gradient fields in the three orthogonal spatial axes with currents given by the gradient amplifier. The gradient coil can also produce various non-linear gradients fields to improve the homogeneity of the main magnetic field. This has the same major technological characteristics as the predicate device. The RF transmission and receive system consists of the RF amplifier, the RF transmission coil and various RF receiver coils for receiving the relaxation signals emitted from the subject after RF transmission. They are coils made of copper wires tuned to transmit and receive around the designed frequency corresponding to the magnetic field strength. This has the same major technological characteristics as the predicate device. The cooling system maintains suitable operating temperatures for amplifiers and other system devices. This has the same major technological characteristics as the predicate device. The patient table and support components provide a comfortable platform for the patient and allows the operator to easily position the patient to the location for imaging. This has the same major technological characteristics as the predicate device. The spectrometer controls the execution of the pulse sequence for RF transmit and receive and gradient output. This has the same major technological characteristics as the predicate device. The server/client PC and the application software provides the operator a platform to configure scans and manage scanned data. Raw data received from the spectrometer is also reconstructed here. This has the

	same major technological characteristics as the predicate device. Therefore, the same scientific technology theory is applied to both the NEONA 1.5T MRI system and predicate device. Any minor differences in physical attributes do not constitute any safety and effectiveness issue, as indicated in performance data provided.

Non-Clinical Testing Summary:	The filing device is claimed to comply with the following cited FDA recognized standards: • AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010(R)2012(Cons.Text) [Incl.AMD2:2021] - Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance [Including Amendment 2 (2021)] • IEC 60601-1-2:2020 Edition 4.1 - Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances - Requirements and Tests [Including Amendment 1 (2021)] • IEC 60601-2-33:2015 - Medical Electrical Equipment - Part 2-33: Particular Requirements for The Basic Safety and Essential Performance of Magnetic Resonance Equipment for Medical Diagnostic • NEMA MS-1-2008 (R2020) - Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Images • 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 6-2008 (R2014) - Determination of Signal-to-Noise Ratio and Image Uniformity for Single-Channel Non-Volume Coils in Diagnostic MR Imaging • NEMA MS 8-2016 - Characterization of The Specific Absorption Rate For Magnetic Resonance Imaging Systems • NEMA MS 9-2008 (R2020) - Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images • NEMA MS 14-2019 - Characterization of Radiofrequency (RF) Coil Heating in Magnetic Resonance Imaging Systems • ISO 10993-1:2018, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process • ISO 10993-5:2009 Edition 3 - Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity • ISO 10993-10:2010 Edition 3 - Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization • Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices, dated November 18, 2016 • Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, dated May 11, 2005 • Magnetic Resonance (MR) Receive-only Coil - Performance Criteria for Safety and Performance Based Pathway, dated December 11, 2020 The performance testing results demonstrate the safety and performance as expected. Therefore, the filing device is substantially equivalent to the legally marketed predicate device.
Clinical Testing Summary:	Sample clinical images are provided to verify the claim of filing device's capability in generating images for diagnostic purposes. Sample clinical image sets from filing device and predicate device on same pulse sequences are provided to demonstrate the substantial equivalence of filing device to legally marketed predicate device.

Conclusions Drawn from Non-Clinical Information and Clinical Images:	The non-clinical information (safety and performance tests), combined with clinical images (both from filing device and predicate device), demonstrate that the filing device is as safe, as effective, and performs as well as the predicate device.

SE Conclusion:	The filing device has the same intended use as the predicate device. The minor differences in indication for use do not constitute any safety and effectiveness issue, as indicated in performance data provided. The filing device utilizes same technologies as predicate device, and gives consistent results (images) in medical diagnosis. Any minor differences in physical attributes do not constitute any safety and effectiveness issue, as indicated in performance data (non-clinical/clinical) provided. Therefore the filing device is demonstrated, for being substantially equivalent to the legally marketed predicate device.

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS ADDITIONAL INFORMATION

Comparison of Technological Characteristics with the Predicate Device:

General	**Filing Device**	**Predicate Device**
Design	Cylindrical	Cylindrical
Materials	FRP, ABS	
Power Source	Isolated power supply	
Performance Data	Comply with: - NEMA MS standards - IEC standards: IEC 60601-1, IEC60601-1-2, IEC60601-2-33	
Magnet	**Filing Device**	**Predicate Device**
Type	Superconducting	
Field Strength	1.5T	
Weight	2,987 kg	3,200 kg
Overall Dimensions	1378 x 1736 x 2148 mm (L x W x H)	1497 x 1880 x 2421 mm (L x W x H)
Cryogen Type	Liquid helium free magnet bore, with 4K cryo-compressor	Liquid Helium
Spatial Homogeneity	3.04 ppm (rms) at 40cm DSV	1.45 ppm at 40 cm DSV
Fringe Field	5 gauss line < 3m radial x 4m axial	5 gauss line < 2.5m radial x 4m axial
Magnet Room Lighting	For sufficient and even lighting, 16 overhead lamps (100 lumen each) recommended	For sufficient and even lighting, 16 overhead lamps (100 lumen each) recommended
Room Ventilation	HVAC is installed for ventilation.	
Gradient System	**Filing Device**	**Predicate Device**
Amplitude	52.0mT/m	43.6 mT/m
Rise time	366µs	0.17 ms
Slew rate	142T/m/s	257 T/m/s
Patient Table	**Filing Device**	**Predicate Device**
Dimensions (L x W x H)	88.6 x 17.8 x 37.3 inch (2250 x 452 x 947 mm)	92.1 x 24.6 x 34.0 inch (2340 x 624 x 864 mm)
Patient positioning	Laser Localizer assisted automatic patient table positioning. Manual Position mode	Laser Localizer assisted automatic patient table positioning. Manual Position mode
Max Patient Weight	200kg	200kg
Patient-control room communication	Microphones and speaker for two-way communication between patient and radiologist	Microphones and speaker for two-way communication between patient and radiologist
Workstation	**Filing Device**	**Predicate Device**
Model	Multi-Processing, Multi-Core PC with 24-inch monitor	Multi-Processing, Multi-Core PC with 24-inch monitor
Memory and Capacity	128GB of RAM, 2TB SSD Storage	64GB of RAM, 250GB SSD Storage
Operating System	Microsoft Windows	Microsoft Windows
Receive Coils	**Filing Device**	**Predicate Device**
Multi-Channel Head Coil	✓	✓
Multi-Channel Head and neck Coil	✓	✓
Multi-Channel Body Coil	✓	✓
Multi-Channel Knee Coil	✓	✓
Pulse Sequences	**Filing Device**	**Predicate Device**
T1 Spin Echo	✓	✓
T1, T2 Fast Spin Echo	✓	✓
T1, T2* Gradient Echo	✓	✓
IRFSE	✓	✓

2D Image Processing Features	Filing Device	Predicate Device
Image panning, zooming, windowing	✓	✓
Image flipping, inverting and rotation	✓	✓
Statistical Analysis	✓	✓
Geometric Measurement	✓	✓
Phase Image	✓	✓
CINE	✓	✓
Shutter	✓	✓
Image Filtering	✓	✓
Image Subtraction	✓	✓
Slice Profile	✓	✓
Histogram	✓	✓
3D Image Processing (MPR/Max.IP)	**Filing Device**	**Predicate Device**
Image panning, zooming, windowing	✓	✓
Cutting Operation Output Stack	✓	✓
Image export	✓	✓
The filing device basically utilizes same technologies as predicate device, and can give consistent results when using the images in medical diagnosis. The minor differences in technological characteristics do not constitute any safety and effectiveness issue, as indicated in performance data provided.		