December 23, 2024

Jiangsu LiCi Medical Device Co., Ltd.
℅ Rachel Yu
Manager
Zhihe Info-Tech (Suzhou) Co., Ltd.
Room 616, Building 1, No. 1 Huayun Road,
Industrial Park, Suzhou City
Jiangsu, Suzhou 215134
China

Re: K242573
Trade/Device Name: NIDO Baby Magnetic Resonance Imaging System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH
Dated: October 31, 2024
Received: October 31, 2024

Dear Rachel Yu:

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.

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,

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242573

Device Name

NIDO Baby Magnetic Resonance Imaging System

Indications for Use *(Describe)*

The NIDO Baby Magnetic Resonance Imaging System is indicated for use as a magnetic resonance imaging device for producing axial, sagittal, coronal and oblique images that displays the internal structure of neonatal or infant head. When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis. The NIDO Baby Magnetic Resonance Imaging System is applicable to neonatal or infant head with circumference of up to 50 cm and weight up to 15Kg.

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.

510(k) summary

I. Submitter

Device Submitter: Jiangsu LiCi Medical Device Co., Ltd.
277 Yuzhou South Road, Haizhou District,
Lianyungang, Jiangsu, China

Contact Person: Bing Keong Li
Title: General Manager
E-mail: joeli@licimedical.com

Date Prepared: August 29, 2024

II Device

Trade Name of Device: NIDO Baby Magnetic Resonance Imaging System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Common Name: Magnetic Resonance Imaging System
Regulatory Class: Class II
Product code: LNH
Review Panel: Radiology

III Predicate Device 1

Trade Name:	Embrace Neonatal MRI System
Regulation Number:	21 CFR 892.1000
Regulation Name:	Magnetic Resonance Diagnostic Device
Regulatory Class:	Class II
Product Code:	LNH
Premarket Notification:	K170978
Manufacturer:	Aspect Imaging Ltd.

IV Predicate Device 2

Trade Name:	Lucy Point-of-Care Magnetic Resonance Imaging Device
Regulation Number:	21 CFR 892.1000
Regulation Name:	Magnetic resonance diagnostic device
Regulatory Class:	Class II
Product Code:	LNH
Premarket Notification:	K192002
Manufacturer:	Hyperfine Research, Inc.

V Device Description

The NIDO Baby Magnetic Resonance Imaging System, model LCM-MRI-3500-01A, is a specialized open-type MRI system designed for neonatal and infant head imaging. The system utilized a 0.35 Tesla (T) permanent magnet to acquire 2D single-slice, multi-slice, and 3D volume images of the brain.

Magnetic Resonance Imaging (MRI) is a non-invasive medical imaging technique that uses strong magnetic fields, radio waves, and a computer to produce detailed images of the internal structures of the body. Unlike X-rays or CT scans, MRI does not use ionizing radiation. Instead, it relies on the magnetic properties of atoms in the body, particularly hydrogen atoms, which are abundant in water and fat. When a patient is placed inside the MRI machine, the powerful magnets that create a strong magnetic field around the patient causes hydrogen atoms in the body to align with the field. Once the hydrogen atoms are aligned, radio waves are sent into the body. These waves temporarily disrupt the alignment of the hydrogen atoms. When the radio waves are turned off, the hydrogen atoms return to their original alignment, emitting signals in the process. These signals are detected by the MRI machine and converted into detailed images of the body's internal structures.

The NIDO Baby Magnetic Resonance Imaging System features a 0.35T permanent magnet with an open U-shaped structure, optimized for MR head imaging of neonatal and infant patients. Key components include the magnet system, gradient system, radio frequency (RF) system, spectrometer system, temperature control system and clinical imaging software. The system’s gradient field strength is ≤32 mT/m with a slew rate of ≤107 T/m/s. Integrated transceive RF head coil also functions as a patient table, operating within a resonance frequency range of 14.6 MHz to 14.9 MHz is used to acquired MR images and to provide patient safety and comfort during scanning. The high-performance computer console is installed with clinical imaging software, which includes a variety of pulse sequences, such as Spin Echo, Fast Spin Echo, Fast Low Angle Shot Gradient Echo, Fluid-Attenuated Inversion Recovery and Diffusion-Weighted Imaging for Proton Density, T1 weighted, T2 weighted and Diffusion imaging.

VI Indications for Use

The NIDO Baby Magnetic Resonance Imaging System is indicated for use as a magnetic resonance imaging device for producing axial, sagittal, coronal and oblique images that displays the internal structure of neonatal or infant head. When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis. The NIDO Baby Magnetic Resonance Imaging System is applicable to neonatal or infant head with circumference

of up to 50 cm and weight up to 15Kg.

VII Substantial Equivalence Discussion

Table VII-1 Substantial equivalence discussion

Items	Subject Device NIDO Baby Magnetic Resonance Imaging System	Predicate Device 1 Embrace Neonatal MRI System (K170978)	Predicate Device 2 Lucy Point-of-Care Magnetic Resonance Imaging Device (K192002)
Indications for Use	The NIDO Baby Magnetic Resonance Imaging System is indicated for use as a magnetic resonance imaging device for producing axial, sagittal, coronal and oblique images that displays the internal structure of neonatal or infant head. When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis. The NIDO Baby Magnetic Resonance Imaging System is applicable to neonatal or infant head with circumference of up to 50 cm and weight up to 15Kg.	The Embrace Neonatal MRI System is indicated for use as a magnetic resonance imaging device for producing axial, sagittal, coronal and oblique images that displays the internal structure of neonatal head with a circumference of up to 38 cm and weight between 1Kg and 4.5 Kg. When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis.	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.
Product Code	LNH	LNH	LNH
Regulation Number	21 CFR 892.1000	21 CFR 892.1000	21 CFR 892.1000
Class	CLASS II	CLASS II	CLASS II
Environment of Use	At the point of care in medical facilities including emergency	Hospital setting	At the point of care in medical facilities including emergency rooms, critical

Items		Subject Device NIDO Baby Magnetic Resonance Imaging System	Predicate Device 1 Embrace Neonatal MRI System (K170978)	Predicate Device 2 Lucy Point-of-Care Magnetic Resonance Imaging Device (K192002)
		rooms, critical care units, hospital.		care units, hospital or rehabilitation rooms.
Anatomical sites		Neonatal or infant head	Neonatal Head	Head
Energy Used and/or Delivered		Magnetic Resonance	Magnetic Resonance	Magnetic Resonance
Patient Population		Neonatal or infant head with circumference of up to 50 cm and weight up to 15Kg.	Neonates with head circumference of up to 38 cm and weight between 1Kg and 4.5 Kg	Adult and pediatric patients (above 2 years old)
Human Factors		The product is designed similar to other commercially available MRI systems and therefore is familiar and easy for use for the user. Furthermore, the device contains a user-friendly software interface through which the user may easily access all device functions.	The Embrace Neonatal MRI System is designed similar to other commercially available MRI Systems and therefore is familiar and easy for use for the user. Furthermore, the device contains a user-friendly software interface through which the user may easily access all device functions.	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.
Magnet	Physical Dimensions	109cm x 83cm x 138.5cm	171cm x 145cm x 220cm	835 mm x 630 mm x 652 mm
	Bore Opening	260mm Wide	184x260mm	610 mm x 315 mm
	Weight	4500Kg	5500(5680 with PB) Kg	320 kg
	Field Strength	0.35Tesla Permanent Magnet	1.0Tesla Permanent Magnet	64 mT permanent magnet
Gradient	Strength	32mT/m	150mT/m	16 mT/m
	Rise Time	0.3mSec	0.3mSec	0.5 ms
	Slew Rate	107T/m/Sec	500T/m/Sec	28 T/m/s
Computer Display		27” LED Display	24” LED Display	User supplied tablet
RF Coils		1 head coil	1 head coil	1 head coil
Coil Type		TX/RX	TX/RX	RX

Items	Subject Device NIDO Baby Magnetic Resonance Imaging System	Predicate Device 1 Embrace Neonatal MRI System (K170978)	Predicate Device 2 Lucy Point-of-Care Magnetic Resonance Imaging Device (K192002)
Coil Geometry	Oval	Cylindrical	Form-fitting
Coil Design	Linear Volume	Linear Volume	Linear Volume
Patient Table Dimensions	139.5cm x 24.5cm x 91.8cm	140cm x 60.6cm x 120cm	N/A
Patient Weight Capacity	15kgs Max	4.5kgs Max	200 kg
Electrical Safety	Evaluated according to IEC 60601-1	Evaluated according to IEC 60601-1	Evaluated according to IEC 60601-1
EMC	Evaluated according to IEC 60601-1-2	Evaluated according to IEC 60601-1-2	Evaluated according to IEC 60601-1-2
Max SAR for Transmit Coil	Evaluated according to IEC 60601-2-33,	Evaluated according to IEC 60601-2-33,	Evaluated according to IEC 60601-2-33,
Max dB/dt	Comply with IEC 60601-2-33	Comply with IEC 60601-2-33	Comply with IEC 60601-2-33
Biocompatibility	Patient contact materials were tested and demonstrated no cytotoxicity (ISO 10993-5), no evidence for irritation and sensitization (ISO 10993-10).	Patient contact materials were tested and demonstrated no cytotoxicity (ISO 10993-5), no evidence for irritation and sensitization (ISO 10993-10).	Patient contact materials were tested and demonstrated no cytotoxicity (ISO 10993-5), no evidence for irritation and sensitization (ISO 10993-10).

The NIDO Baby Magnetic Resonance Imaging System have the same intended use, technology, design and performance specifications are either identical or substantially equivalent to existing legally marketed predicate devices. The differences between the NIDO Baby Magnetic Resonance Imaging System and predicate devices do not alter suitability of the proposed device for its intended use.

VIII Non-Clinical Tests

As part of demonstrating substantial equivalence to the predicate, a risk-based assessment was completed to identify the risks associated with the modifications. Based on the risk assessment, the following verification and validation testing was performed. The subject device passed all the testing in accordance with internal requirements and applicable standards to support substantial equivalence.

Test	Test Description	Applicable Standard(s)
Software Verification	Software verification testing in accordance with the design requirements to ensure that the software requirements were met.	• IEC 62304:2015 • FDA Guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
Image Performance	Testing to verify the subject device meets all image quality criteria.	• NEMA MS-1-2008(R2020) • NEMA MS-2-2008(R2020) • NEMA MS-3-2008(R2020) • NEMA MS-5-2018 • NEMA MS-12-2016
Software Validation	Validation to ensure the subject device meets user needs and performs as intended.	• FDA Guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

The following testing was leveraged from the predicate device. Test results from the predicate were used to support the subject device because the conditions were identical or the subject device modifications did not introduce a new worst-case configuration or scenario for testing.

Test	Test Description	Applicable Standard(s)
Biocompatibility	Biocompatibility testing of patient-contacting materials.	• ISO 10993-1:2018 • ISO 10993-5:2009 • ISO 10993-10:2021 • ISO 10993-23:2021
Safety	Electrical Safety, EMC, and Essential Performance testing.	• IEC 60601-1: 2020 • IEC 60601-1-2:2020 • IEC 60601-1-6:2020 • IEC 60601-2-33:2022 • NEMA MS-4-2010
Performance	Characterization of the Specific Absorption Rate or Magnetic Resonance Imaging Systems.	• NEMA MS-8-2016
Cybersecurity	Testing to verify cybersecurity controls and management.	• Cybersecurity as recommended in FDA guidance, "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices

IX Conclusion

Based on the intended use, technological characteristics, performance results, and comparison to the predicate, the subject NIDO Baby Magnetic Resonance Imaging System has been shown to be substantially equivalent to the predicate device identified in this submission and does not present any new issues of safety or effectiveness.