March 13, 2026

Aspect Imaging, Ltd.
℅ Alex Cadotte
Vice President, Digital Health, AI, and Radiology
Mcra
803 7th St. NW
Washington, District of Columbia 20001

Re: K254277
Trade/Device Name: Embrace Neonatal MRI System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH, MOS
Dated: December 9, 2025
Received: December 30, 2025

Dear Alex Cadotte:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 Management System Regulation (QMSR) (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.

510(k) Number *(if known)*
K254277

Device Name
Embrace Neonatal MRI System

Indications for Use *(Describe)*
The Embrace Neonatal MRI System is indicated for use as a magnetic resonance imaging device for producing axial, sagittal, coronal and oblique images that display the internal structure of neonatal head with 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.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K254277

510(k) Summary

Device Trade Name: Embrace Neonatal MRI System

Manufacturer:
Aspect Imaging LTD
27 Shaked St.
Industrial Area Hevel Modi'in
Shoham 60850, Israel

Contact Person:
Yaron Eshel
VP, Quality Assurance and
Regulatory Affairs
Yaron.Eshel@aspectimaging.com

Prepared by:
MCRA, LLC
803 7th Street, NW, 3rd Floor
Washington, DC 20001
Office: 202.552.5800

Date Prepared: March 10, 2026

Classifications: 21 CFR 892.1000

Class: II

Product Codes: LNH, MOS

Primary Predicate: Embrace Neonatal MRI System (Aspect Imaging, K170978)

Indications For Use:

The Embrace Neonatal MRI System is indicated for use as a magnetic resonance imaging device for producing axial, sagittal, coronal and oblique images that display the internal structure of neonatal head with 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.

Device Description

The Embrace Neonatal MRI System is a 1 Tesla Permanent magnet MRI system producing MR images of the neonatal head. During MRI scan, body parts to be imaged are held within a uniform static magnetic field, and are subject to sequences of RF pulses and gradient magnetic fields. The signal from the precession of the magnetization created by these fields is sampled and processed to produce image data.

Predicate Device:

The purpose of this Traditional 510(k) is to demonstrate that the Embrace Neonatal MRI System (Revision E) is substantially equivalent to predicate device for the purpose of introducing the system to interstate commerce. It has been determined that the Embrace Neonatal MRI System (Revision E) are substantially equivalent to the following predicate:

- **Primary Predicate:** Embrace Neonatal MRI System (Aspect Imaging, K170978)

Specification	**Predicate Device Embrace Neonatal MRI System (K170978)**	**Subject Device Embrace Neonatal MRI System**	**Discussion of Differences**
Product Code	LNH, MOS	LNH, MOS	Same
Classification / Regulation	Magnetic Resonance Diagnostic Device (21 CFR.892.1000)	Magnetic Resonance Diagnostic Device (21 CFR 892.1000)	Same

Specification	Predicate Device Embrace Neonatal MRI System (K170978)	Subject Device Embrace Neonatal MRI System	Discussion of Differences
Intended Use/Indication for Use	The Embrace Neonatal MRI System is indicated for use as a magnetic resonance imaging device for producing axial, sagittal, coronal and oblique images that display the internal structure of neonatal head with 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 Embrace Neonatal MRI System is indicated for use as a magnetic resonance imaging device for producing axial, sagittal, coronal and oblique images that display the internal structure of neonatal head with 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.	Same
Patient Population	Patients requiring MR images of the Neonatal Head	Patients requiring MR images of the Neonatal Head	Same
Anatomical Sites	Neonatal Head	Neonatal Head	Same
Environment of Use	Hospital setting	Hospital setting	Same
Energy Used and/or delivered	Magnetic Resonance	Magnetic Resonance	Same
Human Factors	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.	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.	Same
Hardware Specifications:			
Magnet **-Physical**			Same

Specification	Predicate Device Embrace Neonatal MRI System (K170978)	Subject Device Embrace Neonatal MRI System	Discussion of Differences
Diminutions **-Bore Opening** **-Weight** **-Field Strength**	171×145×229 cm 184×260mm 5500 (5680 with patient bed) Kg 1 Tesla Permanent Magnet	171×145×229 cm 184×260mm 5500 (5680 with patient bed) Kg 1 Tesla Permanent Magnet	
Gradient **-Strength** **-Rise Time** **-Slew Rate**	 150 mT/m 0.300mSec 500 T/m/Sec	 150 mT/m 0.300mSec 500 T/m/Sec	Same
IT infrastructure	Windows PC on workstation table	Windows PC on workstation table	Revision E contains software enhancements for usability and strengthened cybersecurity
Computer Display	24" LED Display	24" LED Display	Same
RF Coils **-Coil Type** **-Coil Geometry** **-Inner dimensions (mm)** **-Coil Design**	1 Head Coils TX/RX Cylindrical 143 Diameter Linear Volume	1 Head Coils TX/RX Cylindrical 143 Diameter Linear Volume	Same
Patient Bad	Integrated patient bed	Integrated patient bed	Improvements to the bed for usability and serviceability are included in revision E
Target population	Neonates with head circumference of up to 38 cm and weight	Neonates with head circumference of up to 38 cm and weight	Same

Specification	Predicate Device Embrace Neonatal MRI System (K170978)	Subject Device Embrace Neonatal MRI System	Discussion of Differences
	between 1Kg and 4.5Kg	between 1Kg and 4.5Kg	
-Dimensions **-Patient weight capacity** **-Compartment length**	60.6cm W x 120cm H x 140cm L 4.5 Kg Max 58 cm	60.6cm W x 120cm H x 140cm L 4.5 Kg Max 58 cm	Same
-Set Temperature **-Warm Up time** **-Temperature control** **-Humidity control** **-MRI compatibility**	20.5°C - 36.5°C 45 minutes Air No Aspect Embrace 1T	20.5°C - 36.5°C 45 minutes Air No Aspect Embrace 1T	Same
Performance Testing			
Imaging Performance: (Recognition no. in brackets)	• **NEMA MS 1** - Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Imaging (12-188) • **NEMA MS 12** - Quantification and Mapping of Geometric Distortion for Special Applications (12-306) • **NEMA MS 2** - Determination of Two-Dimensional Geometric Distortion in Diagnostic Magnetic Resonance Images (12-196) • **NEMA MS 3** - Determination of Image Uniformity in Diagnostic Magnetic Resonance Images (12-187) • **NEMA MS 5** - Determination of Slice	• **NEMA MS 1** - Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Imaging (12-188) • **NEMA MS 12** - Quantification and Mapping of Geometric Distortion for Special Applications (12-306) • **NEMA MS 14** - Characterization of Radiofrequency (RF) Coil Heating in Magnetic Resonance Imaging Systems (12-331) • **NEMA MS 2** - Determination of Two-Dimensional Geometric Distortion in Diagnostic Magnetic Resonance Images (12-196) • **NEMA MS 3** -	MS-14 was added to conform with FDA applicable standards

Specification	Predicate Device Embrace Neonatal MRI System (K170978)	Subject Device Embrace Neonatal MRI System	Discussion of Differences
	Thickness in Diagnostic Magnetic Resonance Imaging (12-322)	Determination of Image Uniformity in Diagnostic Magnetic Resonance Images (12-187) • **NEMA MS 5** - Determination of Slice Thickness in Diagnostic Magnetic Resonance Imaging (12-322)	
Safety Performance: (Recognition no. in brackets)		• **NEMA MS 4** - Acoustic Noise Measurement Procedure for Diagnostic Magnetic Resonance Imaging Devices (12-232) • **NEMA MS 8** - Characterization of the Specific Absorption Rate (SAR) for MRI Systems (12-315)	MS-4 and MS -8 were added to conform with FDA safety standards
Electromagnetic Compatibility, Electrical, Mechanical, and Thermal Safety			
Voluntary consensus standards (Recognition no. in brackets)	• **IEC 60601-1** - Medical equipment/medical electrical equipment - Part 1: General requirements for basic safety and essential performance (19-37) • **IEC 60601-1-2** - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (19-36) • **IEC 60601-2-33** - Medical electrical equipment - Part 2-33: Particular requirements for the basic	• **IEC 60601-1** - Medical equipment/medical electrical equipment - Part 1: General requirements for basic safety and essential performance (19-37) • **IEC 60601-1-2** - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (19-36) • **IEC 60601-2-33** - Medical electrical equipment - Part 2-33: Particular requirements for the	**Voluntary consensus standards** (Recognition no. in brackets)

Specification	Predicate Device Embrace Neonatal MRI System (K170978)	Subject Device Embrace Neonatal MRI System	Discussion of Differences
	safety and essential performance of magnetic resonance equipment for medical diagnosis (12-347) • **IEC 60601-2-20** - Medical Electrical Equipment Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators (6-462) • **IEC 60601-1-6** - Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability (5-132) • **IEC 62304** - Software life-cycle processes (13-79)	basic safety and essential performance of magnetic resonance equipment for medical diagnosis (12-347) • **IEC 60601-2-20** - Medical Electrical Equipment Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators (6-462) • **IEC 60601-1-6** - Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability (5-132) • **IEC 62304** - Software life-cycle processes (13-79)	
Sequence available to the User	• Gradient Echo • Gradient Echo 3D • Spin Echo • Fast Spin Echo • ADC Map Single Shot Splice Axial • ADC Map Spin Echo	• 2D Spin Echo • (SE) 2D Fast Spin Echo (FSE) • 3D Fast Spin Echo (FSE) • 3D Gradient Echo (GRE) • ADC map (Diffusion Weighted imaging with ADC mapping) • 2D Time of Flight (TOF) • 3D Time of Flight (TOF) 2D • Propeller FSE • 2D ADC Propeller	Modification of sequences for the user

Software: In addition, system and software verification and Validation testing were performed to demonstrate performance of the device as part of design controls activity.

Biocompatibility: Patient-contacting materials were assessed per FDA Guidance Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". Patient contact surfaces were classified based on type of contact and duration. All surfaces are considered surface contacting for durations less than or equal to 24

hours. Where required, evidence of testing was provided for endpoints including cytotoxicity, sensitization, and irritation.

All patient contact surfaces of the Embrace Neonatal MRI System (Revision E) meet biocompatibility requirements consistent with contact type and duration.

The following design control activities were applied to the development of the system:

- Risk Management
- Requirements Management
- Design Reviews
- Unit level module verification
- System Integration verification
- Performance verification (see table above for specific testing performed)
- Safety and EMC testing
- Simulated use validation testing
- Sample Phantom images

Substantial Equivalence:

The subject device was demonstrated to be substantially equivalent to the predicate cited above with respect to indications, design materials, function, manufacturing, and performance. The non-clinical tests performed by the company demonstrated that any differences in the Embrace Neonatal MRI System (Revision E) do not raise new questions of safety and effectiveness.

Conclusion:

The subject device and the predicate device have the same intended use, have similar technological characteristics, and are made of the same materials. The subject and predicate devices have similar software and EMC characteristics that were validated via new testing. The data included in this submission demonstrates substantial equivalence to the predicate device listed above. The Embrace Neonatal MRI System (Revision E) is as safe, as effective, and performs as well as, or better, than the predicate device.