January 26, 2026

Eyas Medical Imaging, Inc.
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Dr. Suite #510k
Saint Paul, Minnesota 55114

Re: K253499
Trade/Device Name: Ascent3T Neonatal Magnetic Resonance Imaging System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH
Dated: January 20, 2026
Received: January 20, 2026

Dear Prithul Bom:

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)*

K253499

Device Name

Ascent3T Neonatal Magnetic Resonance Imaging System

Indications for Use *(Describe)*

The Ascent3T Neonatal Magnetic Resonance Imaging System (Ascent3T) is a whole-body magnetic resonance scanner designed for neonates and infants. The system can produce cross-sectional images of the internal structure of the head, body or extremities in any orientation.

Images produced by the Ascent3T show the spatial distribution of protons exhibiting magnetic resonance. Images produced by the Ascent3T, when interpreted by a trained physician, may provide information useful in diagnosis.

The Ascent3T Neonatal Magnetic Resonance Imaging System is suitable for neonates and infants weighing up to 9kg (19.8 lbs).

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

Date of Preparation: November 21, 2025

This 510(k) Summary provides the basis for a determination of substantial equivalence for the Ascent^{3T} Neonatal Magnetic Resonance Imaging System (Ascent^{3T}). Safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Ascent^{3T} Neonatal Magnetic Resonance Imaging System **510(k) Summary Information**		
Submitter:	**Eyas Medical Imaging, Inc.** 1105 Western Avenue Cincinnati, OH 45203 USA	
Primary Contact: **Secondary Contact:**	**Ms. Michelle L. Smith** Director Regulatory Affairs & Quality Assurance Phone: +1.513.345.7850 Email: msmith@eyasmri.com **Ms. Alona Gimpliuk** Regulatory Affairs and Quality Assurance Specialist Phone: +1.513.345.3780 Email: agimpliuk@eyasmri.com	
Device Trade Name:	**Ascent^{3T} Neonatal Magnetic Resonance Imaging System**	
Common Name:	**Magnetic Resonance Imaging System**	
Classification:	**Classification Name:**	System, Nuclear Magnetic Resonance Imaging
	Classification Regulation:	21 CFR 892.1000
	Classification Panel:	Radiology
	Device Class:	Class II
	Primary Product Code:	LNH
	Subsequent Product Code:	Not Applicable

Ascent[3T] Neonatal Magnetic Resonance Imaging System 510(k) Summary Information		
Primary Predicate Device:	**Trade Name:**	Embrace Neonatal MRI System
	Manufacturer:	Aspect Imaging Ltd.
	510(k) Number:	K170978
	Product Code:	LNH
	Subsequent Product Code:	MOS
	Classification Regulation:	21CFR 892.1000
	Classification Name:	Magnetic Resonance Diagnostic Device (MRDD)
	Classification Panel:	Radiology
	Device Class:	Class II
	Clearance Date:	July 19, 2017
Reference Device:	**Trade Name:**	Ingenia MR Systems (Achieva, Intera, Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition)
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K193215
	Product Code(s):	LNH
	Subsequent Product Code:	LNI
	Classification Regulation:	21CFR 892.1000
	Classification Name:	Magnetic Resonance Diagnostic Device (MRDD)
	Classification Panel:	Radiology
	Device Class:	Class II
	Clearance Date:	April 10, 2020

Ascent[3T] Neonatal Magnetic Resonance Imaging System 510(k) Summary Information	
Device Description:	The Ascent[3T] Neonatal Magnetic Resonance Imaging System (Ascent[3T]) is a high-field magnetic resonance imaging system, appropriately sized and optimized for the neonate and infant population, with a format that allows siting near point of care. The Ascent[3T] presents a solution for the technical limitations associated with using an adult-size MRI system and provides clinicians with an improved ability to visualize and diagnose disease in the neonatal patient population. The Ascent[3T] is equipped with a small format superconducting magnet designed for neonate applications. The system is designed to operate at 3.0 Tesla and achieves a high level of homogeneity over a 24cm diameter spherical volume using passive shims. The magnet requires a minimal amount of helium and no quench pipe. These features, in combination with the size and weight of the magnet, support near-patient siting. The Ascent[3T] patient table is detachable and can serve as a patient transport device. The patient table includes a tabletop cradle with features for securing the patient during scanning. The patient table is mobile, providing flexibility in workflow based on institutional needs and preferences. The Ascent[3T] contains a menu of pulse sequences intended to provide the user with a variety of sequences useful for producing images for diagnostic purposes. Key Features of the Ascent[3T]: • 3T superconducting magnet with 25cm patient bore. • Minimal helium capacity (≤ 2 L) with no quench pipe required. • Gradient system: 80 mT/m maximum amplitude per axis, 300 mT/m/ms slew rate per axis. • Real-time SAR monitoring and alerts with Normal and First-Level Controlled Operating Modes. • Capable of producing images in axial, sagittal, coronal, and oblique orientations. • Accommodates neonates and infants weighing up to 9 kg (19.8 lbs). • Detachable, mobile patient table with built-in safety features.
Intended Use: **Indications for Use:**	The Ascent[3T] Neonatal Magnetic Resonance Imaging System (Ascent[3T]) is a whole-body magnetic resonance scanner designed for neonates and infants. The system can produce cross-sectional images of the internal structure of the head, body or extremities in any orientation. Images produced by the Ascent[3T] show the spatial distribution of protons exhibiting magnetic resonance. Images produced by the Ascent[3T], when interpreted by a trained physician, may provide information useful in diagnosis. The Ascent[3T] Neonatal Magnetic Resonance Imaging System is suitable for neonates and infants weighing up to 9kg (19.8lbs).

Ascent[3T] Neonatal Magnetic Resonance Imaging System
510(k) Summary Information

Design Features and Scientific Technology:

Magnetic resonance imaging is a medical imaging technique that uses a magnetic field and radio waves to create highly detailed anatomical images. Magnetic resonance imaging is based on the principle that certain atomic nuclei present in the human body will emit a weak signal when placed in a strong magnetic field and excited by a radio frequency signal at the Larmor frequency of the nuclei of interest. The signals are received and processed by a computer into structural and/or functional images.

Comparison of Technological Characteristics

	Ascent[3T] Subject Device	Embrace Predicate Device K170978	Ingenia Reference Device K193215
Field Strength	3.0 Tesla	1.0 Tesla	1.5T/3.0T
Bore Size (diameter)	25 cm	Integrated neonatal bore	60–70 cm
Patient Population	Neonates and infants ≤ 9 kg (19.8 lbs)	Neonates 1–4.5 kg	All patients (pediatric and adult)
Gradient System	Per Axis: 80 mT/m max amplitude 300 mT/m/ms slew rate	Per Axis: 86 mT/m max amplitude 288 mT/m/ms slew rate	Per Axis: Up to 65 mT/m max amplitude Up to 220 mT/m/ms slew rate
SAR Compliance	Operating Modes: Normal, First Level	Operating Modes: Normal	Operating Modes: Normal, First Level
Imaging Capabilities - Anatomy	Head, body, extremities	Head only	Full body
Imaging Capabilities – Orientation	Axial, sagittal, coronal, oblique	Axial, sagittal, coronal, oblique	Axial, sagittal, coronal, oblique
Cryogen	Minimal helium No quench pipe	N/A Permanent Magnet	Typically, liquid helium Quench pipe required

Performance Testing

Summary of Non-Clinical Performance Data:

Verification and validation testing confirmed that the Ascent[3T] Neonatal MRI System performs safely and effectively. Testing was conducted on a representative, design-controlled system. Performance and Safety were evaluated according to the recognized consensus standards listed below. In all cases, results met established specifications and criteria.

Performance: Imaging

- NEMA MS 1 - 2008 (R2014, R2020): Determination of Signal-to-Noise ratio (SNR) in Diagnostic Magnetic Resonance Imaging
- NEMA MS 2 - 2008 (R2014, R2020): Determination of Two-Dimensional Geometric Distortion in Diagnostic Magnetic Resonance Images
- NEMA MS 3 - 2008 (R2014, R2020): Determination of Image Uniformity in Diagnostic Magnetic Resonance Images
- NEMA MS 5 – 2018: Determination of Slice Thickness in Diagnostic Magnetic Resonance Imaging
- NEMA MS 12 - 2016: Quantification and Mapping of Geometric Distortion for Special Applications

Ascent[3T] Neonatal Magnetic Resonance Imaging System 510(k) Summary Information	
	Performance: Safety • NEMA MS 4 - 2023 Acoustic Noise Measurement Procedure for Diagnostic Magnetic Resonance Imaging (MRI) Devices • NEMA MS 8 - 2016 (R2023) Characterization of the Specific Absorption Rate (SAR) for Magnetic Resonance Imaging Systems
Electromagnetic Compatibility, Electrical, Mechanical, and Thermal Safety	Eyas utilized FDA's Accreditation Scheme for Conformity Assessment (ASCA) Program to demonstrate compliance with FDA-recognized consensus standards for electromagnetic compatibility, electrical, mechanical, and thermal safety. The Ascent[3T] demonstrated compliance with the following U.S. FDA-recognized consensus standards for EMC, Electrical, Mechanical, and Thermal Safety:
Software:	Software verification and validation activities were carried out to demonstrate the Ascent[3T] system software meets established requirements for safety and performance. Verification and validation tasks provide evidence that system software performs as expected. No new risks to safety or performance were identified during test execution.
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 Ascent[3T] meet biocompatibility requirements consistent with contact type and duration.

ASCA Recognition Number	Methods FDA Recognized Standards
19-36	IEC 60601-1-2 Ed4.1 2020-09
19-8	IEC TS 60601-4-2 Edition 1.0 2024-03
19-46	ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R) 2012 & A2:2010/(R)2012 [Incl. AMD2:2021]
5-132	IEC 60601-1-6:2010 Ed.3+A1;A2
12-347	IEC 60601-2-33:2022 Ed.4

Ascent^{3T} Neonatal Magnetic Resonance Imaging System 510(k) Summary Information	
Summary of Clinical Performance Data:	The proposed Ascent^{3T} Neonatal Magnetic Resonance Imaging System did not require clinical studies. Substantial equivalence to the legally marketed predicate device was proven with the verification/validation testing, including non-clinical bench testing and phantom image validation, consistent with FDA expectations for MR imaging devices in vulnerable populations (e.g., neonates). Pulse sequences available on the Ascent^{3T} were tested as part of the Ascent^{3T} MRI System and Software verification and validation activities. Testing was completed using surrogate materials and methods (phantoms, physiology simulators, et cetera). Images collected were reviewed and confirmed by a U.S. Board Certified Radiologist to be suitable for diagnostic use.
Substantial Equivalence Conclusion:	The Ascent^{3T} Neonatal MRI System is substantially equivalent to the Embrace Neonatal MRI System (K170978) and aligns with performance characteristics of the Philips Achieva/Intera/Ingenia reference devices (K193215). All identified technological differences have been mitigated through rigorous design controls, risk analysis, and performance testing. No new questions of safety or effectiveness are raised by the subject device.