DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Aspect Imaging Ltd.
% Israel Citron
Vice President Quality Assurance and Regulatory Affairs
27 Shaked Street
Industrial Area, Hevel Modi'in
P.O. Box 926
Shoham, 6085001 Israel

July 20, 2017

Re: k170978
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
Dated: June 4, 2017
Received: June 7, 2017

Dear Israel Citron:

This letter corrects our substantially equivalent letter of July 19, 2017.

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

For

Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

k170978

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 displays 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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510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	March 28, 2017
Submitter:	Aspect Imaging Ltd. 27 Shaked St. Industrial Area Hevel Modi'in P.O. Box 926 Shoham, 6085001 ISRAEL
Primary Contact Person:	Israel A. Citron VP Quality Assurance and Regulatory Affairs Aspect Imaging LTD Tel: +972-73-223-9000 Ext 90 Fax: +972-3-716-5606 E mail: icitron@aspectimaging.com
Device Trade Name:	Embrace Neonatal MRI System
Common/Usual Name:	MRI System
Product Classification	II
Classification Name:	Magnetic Resonance Diagnostic Device (21 CFR 892.1000)
Product Code:	LNH, MOS
Predicate Device(s):	K160185 Wrist 3 MRI System
Reference Device(s)	K161918 SREE MRI Transport Incubator* *referenced for the Patient Bed main specifications
Device Description:	The **Embrace Neonatal MRI System** is a 1Tesla Permanent MRI system producing MR images of 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.
Intended 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 displays 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.

Technology: The **Embrace Neonatal MRI System** employs the same fundamental scientific technology as its predicate device (Wrist 3 MRI System K160185).

Comparison of Specifications	**Predicate Device Wrist 3 MRI System (K160185)**	**Proposed Device Embrace Neonatal MRI System**
Intended Use/Indication for Use	The **Wrist 3** MRI System is intended for use as a magnetic resonance imaging device for producing axial, sagittal, coronal, and oblique images of the internal structure of the Wrist and Hand. 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 displays 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.
Patient Population	Patients requiring MR images of the wrist and Hand	Patients requiring MR images of the Neonatal Head
Anatomical Sites	Wrist and Hand	Neonatal Head
Environment of Use	Hospital or clinical setting	Hospital setting
Energy Used and/or delivered	Magnetic Resonance	Magnetic Resonance
Human Factors	The Wrist 3 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.
Hardware Changes		
Magnet:		
- Physical Dimensions	138x87x82 cm	171x145x229 cm
- Bore opening	85x220 mm	184x260 mm
- Weight	1300 (1700 with Trolley) Kg	5500 (5680 with PB) Kg
- Field Strength	1 Tesla Permanent Magnet	1 Tesla Permanent Magnet
Gradient:		
-Strength	215 mT/m	150 mT/m
-Rise Time	0.2 mSec	0.3 mSec
-Slew Rate	1074 T/m/Sec	500 T/m/Sec
Computer:		
-Display:	15″ Touch Display	24″ LED Display
RF Coils	2 Coils: Small/Large	1 Head Coils
Coil Type	TX/RX	TX/RX

Coil Geometry	Oval	Cylindrical
Inner dimensions (mm)	60X100X169 / 75X135X192	143 Diameter
Coil Design	Linear Volume	Linear Volume
Patient Bed: Comparison of Specifications	**Reference device SREE MRI Transport Incubator (K161918)**	**Proposed Device Embrace Neonatal MRI System**
Target population	pre- and term newborns and infants up to 1 month of age and 4.5Kg whole body weight or 55cm whole body length (21.7”).	neonates with head circumference of up to 38 cm and weight between 1Kg and 4.5 Kg
-Dimensions	121.9cm L x 40.6cm W x 30.5cn H	60.6cm W x 120cm H x 140cm L
-Patient weight capacity	4.5Kg Max	4.5 Kg Max
Compartment length	55 cm	58 cm
Set Temperature	28 ºC - 39ºC	20.5 ºC - 36.5ºC
Warm Up time	45 minutes	50 minutes
Temperature control	Air	Air
Humidity control	no	no
MRI compatibility	1.5 and 3 T	Aspect Embrace 1T

Determination of Substantial Equivalence:

Summary of Nonclinical Testing:

The **Embrace Neonatal MRI System** and its applications were tested to comply with the below voluntary consensus standards.

- ES/IEC 60601-1
- IEC 60601-1-2
- IEC 60601-2-33
- IEC 60601-2-20
- IEC 60601-1-6
- IEC 62304
- NEMA MS-1
- NEMA MS-2
- NEMA MS-3
- NEMA MS-5
- NEMA MS-12

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

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
- Safety and EMC testing
- Simulated use validation testing
- Sample phantom images

Summary of Clinical Tests:

The subject of this premarket submission, **Embrace Neonatal MRI System**, did not require clinical studies to support substantial equivalence. Since neonates are a vulnerable patient population, for this particular device, the benefits of sample clinical images did not outweigh the risks associated with acquisition of those images. Therefore, substantial equivalence of the Embrace Neonatal MRI System was determined based on phantom images that demonstrate the ability of the system to provide diagnostic quality images, and sample clinical images of the neonatal head were not necessary to support the premarket submission for this device.

Conclusion: Based on bench testing and phantom image studies, Aspect Imaging LTD believes the Embrace Neonatal MRI System is as safe, as effective, as its predicate device and did not raise new safety or effectiveness issues.

Aspect Imaging LTD considers the Embrace Neonatal MRI system to be substantially equivalent to its predicate device.