Deerfield Imaging, Inc. dba IMRIS
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
SAINT PAUL MN 55114

August 23, 2021

Re: K212367
Trade/Device Name: IMRIS iMRI 3T V
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH, LNI, MOS
Dated: July 29, 2021
Received: July 30, 2021

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 (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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*

K212367

Device Name
IMRIS iMRI 3T V System

Indications for Use *(Describe)*

The IMRIS iMRI 3T V is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra, and that displays the internal structure and/or function of the head, body or extremities.

Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, contrast agents may be used. These images and/or spectra and the physical parameters derived from the images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

The IMRIS iMRI 3T V system may also be used for imaging during intra-operative and interventional procedures when performed with MR safe devices or MR conditional devices approved for use with the MR scanner.

The IMRIS iMRI 3T V MRI systems may also be used for imaging in a multi-room suite.

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

This 510(k) summary is submitted in accordance with the requirements of 21 C.F.R. Part §807.92.

1. Submitter's name and address

Submitter:	Deerfield Imaging, Inc. dba IMRIS
	5101 Shady Oak Rd
	Minnetonka, MN 55343
	USA
	Establishment Registration Number: 3010326005
Date Prepared:	May 3, 2021
Contact Person:	Tracy Brinkmeyer
	VP Quality and Regulatory
Telephone:	(612) 412-6330

Fax: (866) 992-3224 Email: tbrinkmeyer@imris.com

Alternate Contact Person:	Sanjay Shah, P. Eng.
	Regulatory Affairs Consultant
Telephone:	(612) 812-6462
Email:	sshah@imris.com

2. Device Name and Classification

Trade Name:	IMRIS iMRI 3T V
Common Name:	MRDD (Magnetic Resonance Diagnostic Device)
Classification Name:	System, Nuclear Magnetic Resonance Imaging (21 CFR §892.1000)
Product Code:	Primary: LNH Secondary: LNI, MOS

3. Predicate Devices:

Predicate Device Name	510(k)	Decision Date	Product Code	Manufacturer
iMRI 3T S	K133692	Feb 10, 2014	LNH	IMRIS

Reference Device Name	510(k)	Decision Date	Product Code	Manufacturer
MAGNETOM Vida (with syngo MR XA20A)	K192924	March 11, 2020	LNH, LNI,MOS	Siemens Healthcare GmbH

4. Device Description:

The IMRIS iMRI 3T V is a traditional MRI unit that has been suspended on an overhead rail system, and is designed to operate inside an RF shielded room to facilitate intra-operative and multi-room use. The magnet is normally situated in a Diagnostic Room (DR) until imaging is requested. The system retains all standard diagnostic features of an MRI system in the DR. The DR is separated from the intra-operative Operating Room (OR) by sliding doors that are part of the facility structure.

The IMRIS iMRI 3T V is a tool for radiologists and surgeons, used to acquire images for diagnostic, intraoperative, or interventional procedures. For OR purposes, high-resolution images can be obtained immediately prior to surgical incision, intraoperatively, and after wound closure. The IMRIS iMRI 3T V is based on the IMRIS iMRI 3T S cleared under 510(k) K133692 and the Siemens MAGNETOM Vida MRI system cleared under 510(k) K192924. The major components of the IMRIS iMRI 3T V system are: the Siemens MAGNETOM Vida MRI system with minor modifications, IMRIS Magnet Mover System, RF coils, Application platform, OR Table Assembly, Head fixation device, IMRISeye, and Horseshoe headrest.

5. Indications for Use:

The IMRIS iMRI 3T V is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra, and that displays the internal structure and/or function of the head, body or extremities.

Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, contrast agents may be used. These images and/or spectra and the physical parameters derived from the images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

The IMRIS iMRI 3T V system may also be used for imaging during intra-operative and interventional procedures when performed with MR safe devices or MR conditional devices approved for use with the MR scanner.

The IMRIS iMRI 3T V MRI systems may also be used for imaging in a multi-room suite.

6. Comparison with Predicate Devices:

The IMRIS iMRI 3T V is based on the IMRIS iMRI 3T S cleared under 510(k) K133692 and the Siemens MAGNETOM Vida MRI system cleared under 510(k) K192924. There are no changes made to the Siemens syngo® MR software in the IMRIS iMRI 3T V system. The IMRIS iMRI 3T V intra-operative features, including the Magnet Mover Assembly, OR Patient Table, Intra-operative Coils, Application platform, IMRISeye, and Head Fixation Device are substantially equivalent to the same intra-operative features of the predicate iMRI 3T S system. The IMRIS iMRI 3T V does not raise any new safety or effectiveness issues related to the use of a moving MRI system in an intra-operative setting.

7. Standards:

The IMRIS iMRI 3T V conforms to the following FDA recognized consensus standards:

Recognition Number	Product Area	Reference Number and Date	Title of Standard	Standards Development Organization
19-4	General II (ES/ EMC)	ES606011:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012	Medical electrical equipment - Part 1: general requirements for basic safety and essential performance	ANSI /AAMI
19-8	General II (ES/ EMC)	60601-1-2, Ed. 4.0:2014-02	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	IEC
12-295	Radiology	60601-2-33, Ed. 3.2 B:2015	Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis	IEC

Recognition Number	Product Area	Reference Number and Date	Title of Standard	Standards Development Organization
5-125	General I (QS/ RM)	14971:2019	Medical devices - Application of risk management to medical devices	ISO
5-129	General I (QS/ RM)	62366-1:2015+ AMD1:2020	Medical devices – Application of usability engineering to medical devices, including Amendment 1	ANSI AAMI IEC
13-79	Software/ Informatics	62304: Edition 1.1 2015-06	Medical device software - Software life cycle processes	IEC
12-232	Radiology	MS 4:2010	Acoustic Noise Measurement Procedure for Diagnosing Magnetic Resonance Imaging Devices	NEMA
12-288	Radiology	MS 9:2008 (R2014)	Standards Publication Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images	NEMA
12-195	Radiology	MS 6-2008 (R2014)	Determination of Signal-to-Noise Ratio and Image Uniformity for Single-Channel Non-Volume Coils in Diagnostic MR Imaging	NEMA
2-220	Biocompatibility	10993- 1:2009 /(R)2013	Biological evaluation of medical devices - Part 1: evaluation and testing within a risk management process	AAMI ANSI ISO

8. Summary of Studies:

The IMRIS iMRI 3T V has been designed to provide MRI imaging in an intra-operative setting in the same manner as the predicate iMRI 3T S System. The IMRIS iMRI 3T V intra-operative features, including the Magnet Mover Assembly, RF Coils, Application platform, OR Patient Table, Head fixation device, IMRISeye, and Horseshoe headrest are substantially equivalent to the same intra-operative features of the

predicate iMRI 3T S. The IMRIS iMRI 3T V does not raise any new safety or effectiveness issues related to the use of a moving MRI system in an intra-operative setting.

The IMRIS iMRI 3T V does not raise any new safety issues related to static magnetic field effects, changing magnetic field effects, RF heating, acoustic noise, effectiveness issues related to specification volume, signal to noise, image uniformity, and geometric distortion, slice profile, thickness, and gap, or high contrast spatial resolution.

The IMRIS iMRI 3T V verification and validation support a determination of substantial equivalence.

9. Summary of non-clinical data

Design Verification and Validation Test (Bench Testing)

The IMRIS iMRI 3T V system passed the following tests and meets product specifications. IMRIS has performed a number of V&V tests as that includes the following:

- IEC 60601-1 compliance
- IEC 60601-2 compliance
- IEC 60601-2-33 compliance
- Board certified Radiologist confirmation that images produced by the device are of sufficient quality for diagnostic use.

10. Conclusion:

The IMRIS iMRI 3T V has the same intended use and same basic technological characteristics as the predicate device, iMRI 3T S.. While there are some differences in technological characteristics/features compared to the predicate device, the differences have been tested and the conclusions from all verification and validation data suggest that the features bear an equivalent safety and performance profile to that of the predicate device.

The IMRIS iMRI 3T V is substantially equivalent to the predicate device iMRI 3T S (K133692) based on the included studies and analysis.