August 6, 2025

IMRIS Imaging, Inc.
℅ Prithul Bom
Reviewer, Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K252239
Trade/Device Name: InVision™ 3T Recharge Operating Suite
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH, LNI, MOS
Dated: July 17, 2025
Received: July 17, 2025

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252239

Please provide the device trade name(s).

InVision™ 3T Recharge Operating Suite

Please provide your Indications for Use below.

The InVision™ 3T Recharge Operating Suite 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 InVision™ 3T Recharge Operating Suite may also be used for imaging during intraoperative and interventional procedures when performed with MR safe devices or MR conditional devices approved for use with the MR scanner.

The InVision™ 3T Recharge Operating Suite may also be used for imaging in a multi-room suite.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

These 510(k) summaries are submitted in accordance with the requirements of 21 CFR §807.92.

I. SUBMITTER

Establishment:	IMRIS Imaging, Inc. 1230 Chaska Creek Way, Suite 100 Chaska, MN 55318 USA Registration Number: 3010326005
Date Prepared:	June 6, 2025
Contact Person:	Disha Kabrawala
Phone:	732-319-7766

II. DEVICE

Device Name:	InVision™ 3T Recharge Operating Suite
Common Name:	MRDD (Magnetic Resonance Diagnostic Device)
Classification Name:	System, Nuclear Magnetic Resonance Imaging (21 CFR §892.1000)
Regulatory Class:	II
Product Code:	Primary: LNH Secondary: LNI, MOS

III. PREDICATE DEVICE

Device Name:	IMRIS iMRI 3T V
510(k) Number:	K212367
Common Name:	MRDD (Magnetic Resonance Diagnostic Device)
Classification Name:	System, Nuclear Magnetic Resonance Imaging (21 CFR §892.1000)
Regulatory Class	II
Product Code:	Primary: LNH Secondary: LNI, MOS

The reference device used in the submission is the K220589 Siemens MAGNETOM Skyra Fit.

IV. DEVICE DESCRIPTION

The proposed InVision™ 3T Recharge Operating Suite featuring the Siemens MAGNETOM Skyra Fit upgrade from Verio is a traditional Magnetic Resonance Imaging (MRI) scanner that is suspended on an overhead rail system. It is designed to operate inside a Radio Frequency (RF) shielded room to facilitate intraoperative and multi-room use. The InVision™ 3T Recharge Operating Suite uses a scanner, the Siemens MAGNETOM Skyra Fit (K220589, reference device), to produce images of the internal structures of the head as well as the whole body. The

Siemens 3T MAGNETOM Skyra Fit MRI scanner is an actively shielded magnet with a magnetic field strength of 3 Tesla.

The InVision™ 3T Recharge Operating Suite provides surgeons with access to magnetic resonance (MR) images while in the surgical field without changing the surgical/clinical workflow. When images are requested in the operating room (OR), the magnet is moved from the diagnostic room (DR) to the OR on a pair of overhead rails while the patient remains stationary during the procedure. Imaging is performed and once complete the magnet is moved out of the OR to the DR. The magnet can be moved in and out of the surgical field multiple times, as required, throughout the course of the surgical procedure. When the Siemens MAGNETOM Skyra Fit MRI scanner is in the DR, the OR may be used as a standard OR, utilizing standard surgical instruments and equipment during surgery. When not required in the OR, the scanner is available for use in the DR as a standard diagnostic MRI.

V. INDICATIONS FOR USE

The InVision™ 3T Recharge Operating Suite 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 InVision™ 3T Recharge Operating Suite may also be used for imaging during intraoperative and interventional procedures when performed with MR safe devices or MR conditional devices approved for use with the MR scanner.

The InVision™ 3T Recharge Operating Suite may also be used for imaging in a multi-room suite.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The proposed InVision™ 3T Recharge Operating Suite is shown to be substantially equivalent to the predicate device IMRIS iMRI 3T V by comparing the indications for use, principles of operation, technological characteristics, and performance testing similarities and differences. The imaging functionality and software in the Siemens MAGNETOM Skyra Fit is not modified from the standard floor-based Siemens MAGNETOM Skyra Fit (K220589, reference device). The accessories used in the InVision™ 3T Recharge Operating Suite, including the Intraoperative Imaging Coils, IMRISmatrix 5, ORT400 Operating Room Table, Head Fixation Device (HFD100), Doro Lucent iMRI Set, Horseshoe Headrest, and IMRISeye, are substantially equivalent to the predicate iMRI 3T V accessories. The technological characteristic difference between the proposed InVision™ 3T Recharge Operating Suite and the IMRIS iMRI 3T V predicate device is that the predicate device includes the Siemens MAGNETOM Vida (K192924) scanner while the proposed device uses the Siemens MAGNETOM Skyra Fit

scanner. Due to the difference in Siemens MRI scanner, the proposed device incorporates changes to magnet mover components and updates to the modifications made to the Siemens scanner when it is integrated with the InVision™ 3T Recharge Operating suite (see Table 1). The technological characteristic difference rationale demonstrates that the proposed device is safe and effective as a legally marketed predicate device and does not raise different questions of safety and effectiveness.

Table 1 – Substantial Equivalence

Characteristic	Predicate Device IMRIS iMRI 3T V K212367	Proposed Device InVision™ 3T Recharge Operating Suite	Equivalence Comparison
Regulation Number	21 CFR §892. 1000	21 CFR §892. 1000	**Same**
Regulation Name	Magnetic resonance diagnostic device	Magnetic resonance diagnostic device	**Same**
Product Code	Primary: LNH Secondary: LNI, MOS	Primary: LNH Secondary: LNI, MOS	**Same**
Classification	Class II	Class II	**Same**
Panel	Radiology	Radiology	**Same**
Intended Use/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	The InVision™ 3T Recharge Operating Suite 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	**Same**

Characteristic	Predicate Device IMRIS iMRI 3T V K212367	Proposed Device InVision™ 3T Recharge Operating Suite	Equivalence Comparison
	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.	information that may assist in diagnosis. The InVision™ 3T Recharge Operating Suite 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 InVision™ 3T Recharge Operating Suite may also be used for imaging in a multi-room suite.	
Siemens MAGNETOM MRI System	Siemens 3T MAGNETOM Vida (K192924)	Siemens 3T MAGNETOM Skyra Fit (K220589)	**Different**
Static field strength of magnet	3 Tesla	3 Tesla	**Same**
Type of magnet	Superconducting, Actively Shielded	Superconducting, Actively Shielded	**Same**
Where used	Hospital operating room and diagnostic room	Hospital operating room and diagnostic room	**Same**
IMRIS Operating Suite room configurations	• OR1-DR • DR-OR2 • OR1-DR90T • OR1-DR90 • DR90-OR2 • OR1-DR-OR2 • OR1-DR90-OR2 • OR1-DR90T-OR2 • OR1-DR|CB • OR1-DR90|CB • OR1-DR90T|CB • CB|DR-OR2 • CB|DR90-OR2	• OR1-DR • DR-OR2 • OR1-DR-OR2 • OR1-DR|CB • CB|DR-OR2	**Same**

Characteristic	Predicate Device IMRIS iMRI 3T V K212367	Proposed Device InVision™ 3T Recharge Operating Suite	Equivalence Comparison
IMRIS Intraoperative Imaging Coils and coil interface cables	HC300 Coil (K103506)	HC300 Coil (K103506)	**Same**
	Coil interface cables to connect and use Siemens RF coils in intraoperative settings	Coil interface cables to connect and use Siemens RF coils in intraoperative settings	**Same**
Rail system (*2 room and 3 room*)	• Stainless steel rails • Rail covers • Mounting clamp block assembly • Rail accessories • Striker bar • End stops • Limit switches	• Stainless steel rails • Rail covers • Mounting clamp block assembly • Rail accessories • Striker bar • End stops • Limit switches	**Same**
Magnet mover System	Steel and stainless steel, Hangers, stabilizers	Steel and stainless steel, Hangers, stabilizers	**Same**
Turret assembly	Mechanical assembly that allows the magnet to rotate between 0° and 180°.	Mechanical assembly that allows the magnet to rotate between 0° and 180°.	**Similar**
Quench management	Flexible stainless steel quench line	Flexible stainless steel quench line	**Similar**
Cable management	Flexible cable carrier	Flexible cable carrier	**Same**
Collision detection system	Integrated Pressure Activated Collision-detection System (IPACS)	Integrated Pressure Activated Collision-detection System (IPACS)	**Similar**
Manual backup system	Manual crank	Manual crank	**Same**
Covers	Customized by IMRIS to accommodate the magnet mover, mounted side display, RF/air cover, collision detection system, and mounted docking station.	Customized by IMRIS to accommodate the magnet mover, mounted side display, RF/air cover, collision detection system, and mounted docking station.	**Similar**
RF switch	Multi-channel double-throw electronic switch, located	Multi-channel double-throw electronic switch, located	**Same**

Characteristic	Predicate Device IMRIS iMRI 3T V K212367	Proposed Device InVision™ 3T Recharge Operating Suite	Equivalence Comparison
	between the RF slide connectors and the Siemens digital receiver.	between the RF slide connectors and the Siemens digital receiver.	
Table emulator system	Mounted docking station	Mounted docking station	**Similar**
	Table emulator	Table emulator	**Same**
Mounted side display	Handheld pendant and side control panel	Handheld pendant and side control panel	**Similar**
	System status screen displays to assist the operator with Application Platform interface	System status screen displays to assist the operator with Application Platform interface	**Same**
Software	Magnet mover software	Magnet mover software	**Different**
Application Platform	VISIUSmatrix 4	IMRISmatrix 5	**Different**
Surgical table in the OR	ORT400 (Baxter TruSystem 7500)	ORT400 (Baxter TruSystem 7500)	**Same**
Head Fixation Device	HFD100	HFD100	**Same**
Horseshoe Headrest	Horseshoe Headrest	Horseshoe Headrest	**Same**
Patient alignment tool	IMRISeye	IMRISeye	**Similar**
Biocompatibility	Compliant to ISO 10993	Compliant to ISO 10993	**Same**

The InVision™ 3T Recharge Operating Suite conforms to the FDA recognized consensus standards listed in **Table 2**.

Table 2 – FDA Recognized Consensus Standards

Recognition Number	Product Area	Reference Number and Date	Title of Standard	Standards Development Organization
19-46	General II (ES/ EMC)	ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005,	ANSI AAMI

Recognition Number	Product Area	Reference Number and Date	Title of Standard	Standards Development Organization
		/(R)2012 (Cons. Text) [Incl. AMD2:2021]	MOD) [Including Amendment 2 (2021)]	
19-36	General II (ES/ EMC)	IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	IEC
5-125	General I (QS/ RM)	ANSI AAMI ISO 14971:2019	Medical devices - Application of risk management to medical devices	ANSI AAMI ISO
13-79	Software/ Informatics	IEC 62304:2006/A1:2016	Medical device software - Software life cycle	IEC
5-132	General I (ES/ EMC)	IEC 60601-1-6 Edition 3.2 2020-07	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	IEC
12-232	Radiology	NEMA MS 4-2010	Acoustic Noise Measurement Procedure for Diagnosing Magnetic Resonance Imaging Devices	NEMA
12-288	Radiology	NEMA MS 9-2008 (R2020)	Standards Publication Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images	NEMA
12-195	Radiology	NEMA MS 6-2008 (R2020)	Determination of Signal-to-Noise Ratio and Image Uniformity for Single-Channel Non-Volume Coils in Diagnostic MR Imaging	NEMA

Recognition Number	Product Area	Reference Number and Date	Title of Standard	Standards Development Organization
2-258	Biocompatibility	AAMI ANSI ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: evaluation and testing within a risk management process	AAMI ANSI ISO

VII. PERFORMANCE TESTING

The InVision™ 3T Recharge Operating Suite has been designed to provide MR imaging in an intraoperative setting in the same manner as the predicate IMRIS iMRI 3T V (K212367). IMRIS performed testing according to the applicable guidance and regulatory standards to demonstrate that the InVision™ 3T Recharge Operating Suite intraoperative features are substantially equivalent to the intraoperative features of the predicate IMRIS iMRI 3T V. The InVision™ 3T Recharge Operating Suite does not raise any new safety or effectiveness issues related to the use of a moving MRI system in an intraoperative setting. No clinical testing was required to demonstrate substantial equivalence. Clinical images were assessed and provided as required by the guidance document Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices. The InVision™ 3T Recharge Operating Suite has passed performance testing and met product specifications. IMRIS performed non-clinical testing which is summarized in **Table 3**.

Table 3 – Non-Clinical Testing

Testing Performed	Tested Hardware	Source/ Rationale for Test
Non-clinical Performance Testing	InVision™ 3T Recharge Operating Suite (finished device) and applicable components and hardware	*Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices*
Sample Clinical Images in DR and OR	InVision™ 3T Recharge Operating Suite (finished device)	*Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices*
Electrical, mechanical, structural, and related system safety	InVision™ 3T Recharge Operating Suite (finished device)	ANSI /AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]
Electromagnetic compatibility	InVision™ 3T Recharge Operating Suite (finished device)	IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION
Software	InVision™ 3T Recharge Operating Suite (Magnet	*Guidance for the Content of Premarket Submissions for*

	Mover Software and Application Platform Software)	*Software Contained in Medical Devices*

The InVision™ 3T Recharge Operating Suite underwent system functional testing, system imaging performance testing, InVision™ 3T Recharge Operating Suite and Skyra Fit system integration testing, software verification testing, acoustic energy analysis, and heating verification testing.

Verification testing, including functional testing, analysis, and/or inspection, was done for the components and hardware for the side display, cable carrier, covers, quench subsystem, RF switch, table emulator subsystem, magnet mover, and IMRISeye.

The InVision™ 3T Recharge Operating Suite featuring the Siemen's MAGNETOM Skyra Fit has been tested and the conclusions from the verification and validation data support that the technological characteristics of the proposed device have an equivalent safety and performance profile to that of the iMRI 3T V predicate device (K212367). Successful completion of the standard Siemens QA tests and expert review of sample clinical images demonstrates that the InVision™ 3T Recharge Operating Suite maintains clinically acceptable MR imaging performance within both the DR and OR(s). The InVision™ 3T Recharge Operating Suite technological characteristics do not raise different questions of safety and effectiveness. The verification and validation testing of the InVision™ 3T Recharge Operating Suite support a determination of substantial equivalence.

VIII. CONCLUSIONS

The InVision™ 3T Recharge Operating Suite has the same intended use and similar basic technological characteristics as the IMRIS iMRI 3T V (K212367, predicate device). While there are some differences in technological characteristics between the proposed and predicate device, the differences were tested, and verification and validation data suggest that the features bear an equivalent safety and performance profile to that of the predicate device.

IMRIS has concluded that the InVision™ 3T Recharge Operating Suite is substantially equivalent to the currently marketed predicate device IMRIS iMRI 3T V.