Feburary 15, 2024

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

Re: K240157
Trade/Device Name: InVision™ 1.5 Surgical Theatre
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH, LNI, MOS
Dated: January 19, 2024
Received: January 19, 2024

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.

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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K240157

Device Name
InVision™ 1.5 Surgical Theatre

Indications for Use *(Describe)*
The InVision 1.5 Surgical Theatre 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 1.5 Surgical Theatre 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 1.5 Surgical Theatre 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

## I. SUBMITTER

| | |
|---|---|
| **Establishment:** | Deerfield Imaging, Inc.<br>1230 Chaska Creek Way, Suite 100<br>Chaska, MN 55318 USA |
| **Date Prepared:** | December 21, 2023 |
| **Contact Person:** | Liz Ashworth |
| **Phone:** | 218-256-7150 |

## II. DEVICE

| | |
|---|---|
| **Device Name:** | InVision™ 1.5 Surgical Theatre |
| **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<br>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<br>Secondary: LNI, MOS |

The reference device used in the submission is the K203443 Siemens MAGNETOM Sola.

## IV. DEVICE DESCRIPTION

The proposed InVision™ 1.5 Surgical Theatre 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 1.5 Surgical Theatre uses a scanner, the Siemens MAGNETOM Sola (K203443, reference device), to produce images of the internal structures of the head as well as the whole body. The Siemens 1.5T MAGNETOM Sola MRI scanner is an actively shielded magnet with a magnetic field strength of 1.5 Tesla.

The InVision 1.5 Surgical Theatre 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 Sola 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 1.5 Surgical Theatre 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 1.5 Surgical Theatre 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 1.5 Surgical Theatre may also be used for imaging in a multi-room suite.

## VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The proposed InVision 1.5 Surgical Theatre is shown to be substantially equivalent to the predicate device IMRIS iMRI 3T V (K212367) 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 Sola MRI is not modified from the standard floor-based Siemens MAGNETOM Sola (K203443, reference device). The accessories used in the InVision 1.5 Surgical Theatre, including the Intraoperative Imaging Coils, VISIUSmatrix, ORT400 Operating Room Table, Head Fixation Device (HFD100), Horseshoe Headrest, and IMRISeye, are substantially equivalent to the predicate IMRIS iMRI 3T V accessories. The technological characteristic difference between the proposed InVision 1.5 Surgical Theatre and the IMRIS iMRI 3T V predicate device is that the predicate device includes the Siemens MAGNETOM Vida scanner while the proposed device uses the Siemens MAGNETOM Sola 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 1.5 Surgical Theatre (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<br>iMRI 3T V<br>K212367 | Proposed Device<br>InVision 1.5 Surgical Theatre | 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<br>Secondary: LNI, MOS | Primary: LNH<br>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.<br><br>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.<br><br>The IMRIS iMRI 3T V system may also be used for imaging during intra-operative | The InVision 1.5 Surgical Theatre 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.<br><br>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.<br><br>The InVision 1.5 Surgical Theatre may also be used for imaging during intra-operative | **Same** |

| Characteristic | Predicate Device<br>iMRI 3T V<br>K212367 | Proposed Device<br>InVision 1.5 Surgical Theatre | Equivalence Comparison |
|---|---|---|---|
| | and interventional procedures when performed with MR safe devices or MR conditional devices approved for use with the MR scanner.<br><br>The IMRIS iMRI 3T V MRI systems may also be used for imaging in a multi-room suite. | and interventional procedures when performed with MR safe devices or MR conditional devices approved for use with the MR scanner.<br><br>The InVision 1.5 Surgical Theatre may also be used for imaging in a multi-room suite. | |
| Siemens MAGNETOM MRI System | Siemens 3T MAGNETOM Vida (K192924) | Siemens 1.5T MAGNETOM Sola (K203443) | **Different** |
| Static field strength of magnet | 3 Tesla | 1.5 Tesla | **Different** |
| 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 Surgical Theatre room configurations | • OR1-DR<br>• DR-OR2<br>• OR1-DR90T<br>• OR1-DR90<br>• DR90-OR2<br>• OR1-DR-OR2<br>• OR1-DR90-OR2<br>• OR1-DR90T-OR2<br>• OR1-DR\|CB<br>• OR1-DR90\|CB<br>• OR1-DR90T\|CB<br>• CB\|DR-OR2<br>• CB\|DR90-OR2 | • OR1-DR<br>• DR-OR2<br>• OR1-DR90T<br>• OR1-DR90<br>• DR90-OR2<br>• OR1-DR-OR2<br>• OR1-DR90-OR2<br>• OR1-DR90T-OR2<br>• OR1-DR\|CB<br>• OR1-DR90\|CB<br>• OR1-DR90T\|CB<br>• CB\|DR-OR2<br>• CB\|DR90-OR2 | **Same** |
| Siemens diagnostic RF coils | Siemens standard RF coils | Siemens standard RF coils | **Same** |
| IMRIS Intraoperative Imaging Coils | HC300 Coil (K103506) | HC150 Coil (K103506) | **Similar** |

| Characteristic | Predicate Device<br>iMRI 3T V<br>K212367 | Proposed Device<br>InVision 1.5 Surgical Theatre | Equivalence Comparison |
|---|---|---|---|
| and coil interface cables | InSitu Coil 3T (K123091) | InSitu Coil 1.5T (K123091) | **Similar** |
| | 3T coil interface cables to connect and use Siemens RF coils in intraoperative settings | 1.5T coil interface cables to connect and use Siemens RF coils in intraoperative settings | **Similar** |
| Rail system (*2 room and 3 room*) | • Stainless steel rails<br>• Rail covers<br>• Mounting clamp block assembly<br>• Rail accessories<br>• Striker bar<br>• End stops<br>• Limit switches | • Stainless steel rails<br>• Rail covers<br>• Mounting clamp block assembly<br>• Rail accessories<br>• Striker bar<br>• End stops<br>• Limit switches | **Same** |
| Magnet mover material | Steel and stainless steel | Steel and stainless steel | **Same** |
| Mounting mechanism | Overhead rail beam and carriage with acetal rollers | Overhead rail beam and carriage with acetal rollers | **Same** |
| Cable guards | Mechanical guards to protect cabling from magnet mover turret and hangers. | Mechanical guards to protect cabling from magnet mover turret. | **Similar** |
| Hangers, stabilizers | Mechanical interfaces to connect the magnet mover structure. | Mechanical interfaces to connect the magnet mover structure. | **Similar** |
| 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°. | **Same** |
| Side carriages | Mechanical interface to connect the mover assembly to the ceiling mounted rails. | Mechanical interface to connect the mover assembly to the ceiling mounted rails. | **Same** |
| Quench management | Flexible stainless steel quench line | Flexible stainless steel quench line | **Same** |
| Quench manifold | Mechanical interface to connect the quench line. | Mechanical interface to connect the 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** |

| Characteristic | Predicate Device<br>iMRI 3T V<br>K212367 | Proposed Device<br>InVision 1.5 Surgical Theatre | Equivalence Comparison |
|---|---|---|---|
| Magnet mover covers | Cover components that wrap the magnet mover and are stationary with respect to the mover. | Cover components that wrap the magnet mover and are stationary with respect to the mover. | **Same** |
| Magnet 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** |
| Intermediate covers | Cover the gap between the magnet covers and the magnet mover covers. | Cover the gap between the magnet covers and the magnet mover covers. | **Similar** |
| Ramp connection assembly | Provides electrical connections and supporting mechanical bracketry to ramp the magnet, custom placement for IMRIS systems. | Provides electrical connections and supporting mechanical bracketry to ramp the magnet, custom placement for IMRIS systems. | **Similar** |
| Intraoperative RF coil connectors | Front of magnet | Front of magnet | **Same** |
| RF switch | Multi-channel double-throw electronic switch, located between the RF slide connectors and the Siemens digital receiver. | Multi-channel double-throw electronic switch, located between the RF slide connectors and the Siemens digital receiver. | **Same** |
| RF/air cover | Connection interface for user interacting components (RF coils, patient headphones, and panic squeeze ball) on the front of the magnet. | Connection interface for user interacting components (RF coils, patient headphones, and panic squeeze ball) on the front of the magnet. | **Similar** |
| Table emulator system | Mounted docking station | Mounted docking station | **Similar** |
| | Table emulator | Table emulator | **Same** |
| Gradient cable | 16.5 meters | 16.5 meters | **Same** |
| Mounted side display | Handheld pendant and side control panel | Handheld pendant and side control panel | **Similar** |

| Characteristic | Predicate Device iMRI 3T V K212367 | Proposed Device InVision 1.5 Surgical Theatre | Equivalence Comparison |
|---|---|---|---|
| | 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** |
| Drive mechanism | Friction based, belt driven drive rollers | Friction based, belt driven drive rollers | **Same** |
| Position control | Safety limit switches | Safety limit switches | **Same** |
| Software | Magnet mover software | Magnet mover software | **Same** |
| 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** |
| Tissue-contacting components and materials | • Siemens MAGNETOM BioMatrix patient table<br>• Siemens Nexaris table<br>• Siemens BioMatrix diagnostic RF coils<br>• HC300 Coil<br>• InSitu Coil 3T<br>• HFD100<br>• ORT400 table<br>• Horseshoe Headrest | • Siemens MAGNETOM BioMatrix patient table<br>• Siemens Nexaris table<br>• Siemens BioMatrix diagnostic RF coils<br>• HC150 Coil<br>• InSitu Coil 1.5T<br>• HFD100<br>• ORT400 table<br>• Horseshoe Headrest | **Same** |
| Biocompatibility | Compliant to ISO 10993 | Compliant to ISO 10993 | **Same** |
| Sterilization | Compliant to ISO 11135 | Compliant to ISO 11135 | **Same** |

The InVision 1.5 Surgical Theatre 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 /(R)2012 (Cons. Text) [Incl. AMD2:2021] | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)] | ANSI AAMI |
| 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) | ISO 14971 Third Edition 2019-12 | Medical devices - Application of risk management to medical devices | ISO |
| 5-129 | General I (QS/ RM) | IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION | Medical devices - Part 1: Application of usability engineering to medical devices | IEC |
| 13-79 | Software/ Informatics | IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION | Medical device software - Software life cycle processes | 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 | NEMA |

| Recognition Number | Product Area | Reference Number and Date | Title of Standard | Standards Development Organization |
|---|---|---|---|---|
| | | | Resonance Images | |
| 12-195 | Radiology | NEMA MS 6-2008 (R2014, R2020) | Determination of Signal-to-Noise Ratio and Image Uniformity for Single-Channel Non-Volume Coils in Diagnostic MR Imaging | NEMA |
| 2-258 | Biocompatibility | ISO 10993-1 Fifth edition 2018-08 | Biological evaluation of medical devices - Part 1: evaluation and testing within a risk management process | ISO |
| 14-529 | Sterility | ISO 11135 Second edition 2014-07-15 | Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices [Including: Amendment 1 (2018)] | ISO |
| 14-530 | Sterility | ISO 11607-1 Second edition 2019-02 | Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems | ISO |

## VII. PERFORMANCE TESTING

The InVision 1.5 Surgical Theatre 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 1.5 Surgical Theatre intraoperative features are substantially equivalent to the intraoperative features of the predicate IMRIS iMRI 3T V. The InVision 1.5 Surgical Theatre 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 1.5 Surgical Theatre

non-clinical testing is summarized in **Table 3**.

**Table 3 – Non-Clinical Testing**

| Testing Performed | Tested Hardware | Source/ Rationale for Test |
|---|---|---|
| Performance Testing | InVision 1.5 Surgical Theatre (finished device) and applicable components and hardware | *Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices* |
| Sample Clinical Images in DR and OR | InVision 1.5 Surgical Theatre (finished device) | *Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices* |
| Electrical, mechanical, structural, and related system | InVision 1.5 Surgical Theatre (finished device) | ANSI /AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] |
| Electrical safety and electromagnetic compatibility | InVision 1.5 Surgical Theatre (finished device) | IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION |

The InVision 1.5 Surgical Theatre underwent system functional testing, system imaging performance testing, InVision 1.5 Surgical Theatre and Sola 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 1.5 Surgical Theatre 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 IMRIS 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 1.5 Surgical Theatre maintains clinically acceptable MR imaging performance within both the DR and OR(s). The InVision 1.5 Surgical Theatre technological characteristics do not raise different questions of safety and effectiveness. The verification and validation testing of the InVision 1.5 Surgical Theatre support a determination of substantial equivalence.

## VIII. CONCLUSIONS

The InVision 1.5 Surgical Theatre 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 1.5 Surgical Theatre is substantially equivalent to the currently marketed predicate device IMRIS iMRI 3T V.