February 24, 2026

Philips Image Guided Therapy Corporation
Jeff Rongero
Principal Regulatory Affairs Specialist
9965 Federal Dr.
Colorado Springs, Colorado 80921

Re: K253714
Trade/Device Name: IntraSight Plus
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO, DSK, OWB, DSA
Dated: November 21, 2025
Received: November 24, 2025

Dear Jeff Rongero:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

Aneesh S. Deoras -S

Aneesh Deoras
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular Devices
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. | K253714 |

Please provide the device trade name(s).

IntraSight Plus

Please provide your Indications for Use below.

IntraSight Plus is a multi-function system intended to be used as an adjunct diagnostic tool for qualitative and quantitative evaluation of vascular morphology in coronary arteries and peripheral vasculature in patients eligible for endovascular procedures.

The system, when configured with optional features, can also be used for:
- quantitative evaluation of coronary physiology using pressure-derived ratios,
- quantitative evaluation of coronary artery dimensions,
- enhanced visualization of stent or balloon placement in coronary arteries, and
- co-registration of an x-ray image with coronary intravascular ultrasound and/or coronary pressure-derived ratios

in patients eligible for percutaneous coronary intervention.

The IntraSight Plus IVUS function is indicated for use in patients undergoing conventional angiographic procedure to assess vascular morphology and to assess the need for additional treatment post percutaneous intervention. IVUS is obtained with a compatible ultrasound catheter and used as an adjunct to examine vascular morphology in the coronary arteries and vessels of the peripheral vasculature.

The IntraSight Plus FFR and iFR functions are indicated for use in patients with signs of coronary artery disease undergoing coronary catheterization procedures to assess the hemodynamic significance of coronary lesions that may contribute to myocardial ischemia. FFR and iFR are obtained with a compatible pressure guide wire.

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

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

## *014_05: 510(k) Summary*

**As Required by 21 CFR 807.92:**

| | |
|---|---|
| **Submitter:** | **Philips Image Guided Therapy Corporation** |
| **Address:** | 3721 Valley Centre Drive<br>Suite 500<br>San Diego, CA 92130<br>United States |
| **Telephone Number:** | +1 (617) 245-5416 |
| **Contact Person:** | Jeff Rongero |

| | |
|---|---|
| **Date Prepared:** | February 12, 2026 |

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|---|---|---|---|---|---|
| **Device Name:** | IntraSight Plus | | | | |
| **Trade Name:** | IntraSight Plus | | | | |
| **Common Name:** | System, Imaging, Pulsed Echo, Ultrasonic | | | | |
| **Classification Name:** | **Panel** | **Cardiovascular** | | **Radiology** | |
| | **21 CFR Regulation Number** | 870.1110 | 870.2900 | 892.1560 | 892.1650 |
| | **21 CFR Regulation Description** | Blood pressure computer | Patient transducer and electrode cable (including connector) | Ultrasonic pulsed echo imaging system | Interventional fluoroscopic x-ray system |
| | **Class** | II | II | II | II |
| | **Product Code** | DSK | DSA | IYO | OWB |

| **Predicate Device(s):** | **510(k) No.** | **Device Name** | **Product Code(s)** |
|---|---|---|---|
| | K190078 | IntraSight System | IYO, DSA, DSK |
| | K190626 | SyncVision System | OWB |

| **Device Description:** |
|---|
| Philips IntraSight Plus is a multi-modality, application-based platform providing a range of imaging, physiology and co-registration tools. It can be integrated with a compatible interventional X-ray system.<br><br>Philips IntraSight Plus provides qualitative and quantitative evaluation of vascular morphology in the coronary arteries and vessels of the peripheral vasculature in adult patients eligible for endovascular procedures. It is used to support conventional angiographic procedures, providing images of vessel lumen and wall structures. |

| Intended Use and Indications for Use: |
|---|
| IntraSight Plus is a multi-function system intended to be used as an adjunct diagnostic tool for qualitative and quantitative evaluation of vascular morphology in coronary arteries and peripheral vasculature in patients eligible for endovascular procedures.<br><br>The system, when configured with optional features, can also be used for:<br>• quantitative evaluation of coronary physiology using pressure-derived ratios,<br>• quantitative evaluation of coronary artery dimensions,<br>• enhanced visualization of stent or balloon placement in coronary arteries, and<br>• co-registration of an x-ray image with coronary intravascular ultrasound and/or coronary pressure-derived ratios<br>in patients eligible for percutaneous coronary intervention.<br><br>The IntraSight Plus IVUS function is indicated for use in patients undergoing conventional angiographic procedure to assess vascular morphology and to assess the need for additional treatment post percutaneous intervention. IVUS is obtained with a compatible ultrasound catheter and used as an adjunct to examine vascular morphology in the coronary arteries and vessels of the peripheral vasculature.<br><br>The IntraSight Plus FFR and iFR functions are indicated for use in patients with signs of coronary artery disease undergoing coronary catheterization procedures to assess the hemodynamic significance of coronary lesions that may contribute to myocardial ischemia. FFR and iFR are obtained with a compatible pressure guide wire. |

| Comparison of Technological Characteristics: | | | |
|---|---|---|---|
| **Aspect** | **IntraSight Plus (New Device)** | **IntraSight (K190078) SyncVision (K190626)** | **Comparison** |
| **Intended Users** | • Physician<br>• Nurse<br>• Technologist | • Physician<br>• Nurse<br>• Technologist | Same |
| **Intended Environment of Use** | • Indoor<br>• Healthcare Facilities<br>• Cardiac Catheterization Laboratory (Sterile Procedure Room and Non-Sterile Control Room) | • Indoor<br>• Healthcare Facilities<br>• Cardiac Catheterization Laboratory (Sterile Examination Room and Non-Sterile Control Room) | Same |
| **Total Workstations (Control Room)** | • 1 tower | • 2 towers (1 each for IntraSight and SyncVision) | Different |
| **Total Displays (Control Room)** | • 1 display | • 2 displays (1 each for IntraSight and SyncVision) | Different |
| **Total Keyboards and Mice (Control Room)** | • 1 keyboard<br>• 1 mouse | • 2 keyboards (1 each for IntraSight and SyncVision)<br>• 2 mice (1 each for | Different |

| | | | |
|---|---|---|---|
| | | IntraSight and SyncVision) | |
| **Bedside Control Options (Examination / Procedure Room)** | • 1 Touchscreen Module | • 1 Touchscreen Module<br>• 1 Joystick | Different |
| **Bedside Utility Box (BUB) (Examination / Procedure Room)** | • Connects devices in the examination (procedure) room to the workstation in the control room | • Connects devices in the examination (procedure) room to the workstation in the control room | Same |
| **Patient Interface Modules (PIMs) (Examination / Procedure Room)** | • Digital IVUS PIM (also referred to SA-PIM)<br>• Rotational IVUS PIM (also referred to as SpinVision, PIMr)<br>• Functional Measurement (FM) PIM (FM-PIM) | • Digital IVUS PIM (also referred to SA-PIM)<br>• Rotational IVUS PIM (also referred to as SpinVision, PIMr)<br>• Functional Measurement (FM) PIM (FM-PIM) | Same |
| **IVUS Catheters (Examination / Procedure Room)** | • Eagle Eye Platinum<br>• Eagle Eye Platinum ST (Short Tip)<br>• Visions PV .014P<br>• Visions PV .014P RX<br>• Visions PV .018<br>• Visions PV .035<br>• Visions PV .035 Non-Hospital<br>• Reconnaissance PV .018 OTW<br>• Pioneer Plus<br>• Refinity ST (Short Tip) | • Eagle Eye Platinum<br>• Eagle Eye Platinum ST (Short Tip)<br>• Visions PV .014P<br>• Visions PV .014P RX<br>• Visions PV .018<br>• Visions PV .035<br>• Visions PV .035 Non-Hospital<br>• Reconnaissance PV .018 OTW<br>• Pioneer Plus<br>• Refinity ST (Short Tip)<br>• Refinity<br>• Revolution | Different |
| **Pressure Guide Wires (Examination / Procedure Room)** | OmniWire | • Omniwire<br>• Verrata PLUS<br>• Verrata | Different |
| **Software Applications and Functionality** | • IVUS<br>• Functional Measurements (FFR, iFR)<br>• Co-Registration / Tri-Registration<br>• QCA<br>• VE<br>• DD | • IVUS<br>• Functional Measurements (FFR, iFR)<br>• Co-Registration / Tri-Registration<br>• QCA<br>• VE<br>• DD | Same |

| **Non-Clinical Testing:** |
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| The results of non-clinical testing were submitted, referenced, and relied upon to demonstrate the safety and effectiveness of IntraSight Plus and its substantial equivalence to the predicate devices. IntraSight Plus complies with and accounts for FDA recognized consensus standards addressing the |

following:

- Software
- Cybersecurity
- Interoperability
- Electromagnetic compatibility
- Electrical, mechanical, and thermal safety
- Usability
- Packaging validation

**Clinical Testing:**

Not Applicable – IntraSight Plus has the same intended use and indications for use as the predicate devices. Differences in technological characteristics compared to the predicate devices do not raise new or different questions of safety or effectiveness. Therefore, clinical testing was not deemed necessary for IntraSight Plus to demonstrate its safety and effectiveness.

**Conclusion:**

IntraSight Plus has the same intended uses, indications for use, and is intended for the same users within the same intended environments of use as the predicate devices. It meets design verification and validation requirements, including non-clinical testing for software, cybersecurity, interoperability, electromagnetic compatibility, electrical safety, mechanical safety, thermal safety, usability, and packaging.

Differences in technological characteristics primarily reflect the reduction in hardware IntraSight Plus represents due to its merging of predicate device hardware and rendering some of it redundant. The differences do not introduce new intended uses or new indications for use and do not raise new or different questions of safety or effectiveness. IntraSight Plus addresses the differences through non-clinical testing and compliance with appropriate standards, the results of which demonstrate its safety and effectiveness.

Therefore, IntraSight Plus is substantially equivalent to the predicate device IntraSight System (K190078) and predicate device SyncVision System (K190626) with regard to intended uses, indications for use, and technological characteristics.