September 16, 2025

Imaging Engineering LLC
℅ George Jachode
President
4424 NW 13th Street
Suite B12
GAINESVILLE, FL 32609

Re: K251650
Trade/Device Name: Insight Enhanced™ DRF (EN-1002-01)
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: JAA, OWB, OXO
Dated: May 22, 2025
Received: Aug 8, 2025

Dear George Jachode:

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
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: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K251650

Device Name
Insight Enhanced™ DRF (EN-1002-01)

Indications for Use *(Describe)*
Intended for use by a qualified/trained physician or technician for obtaining fluoroscopic and radiographic images of the skull, spinal column, chest, abdomen, and extremities in adult and pediatric patients. Rx only.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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510(k) #: K251650

# 510(k) Summary

Prepared on: 2025-06-11

## Contact Details

21 CFR 807.92(a)(1)

| | |
|---|---|
| Applicant Name | Imaging Engineering LLC |
| Applicant Address | 4424 NW 13th Street Suite B12 Gainesville FL 32609 United States |
| Applicant Contact Telephone | 239.223.1371 |
| Applicant Contact | Mr. George Jachode |
| Applicant Contact Email | g.jachode@imagingengineeringllc.com |

## Device Name

21 CFR 807.92(a)(2)

| | |
|---|---|
| Device Trade Name | Insight Enhanced™ DRF (EN-1002-01) |
| Common Name | Image-intensified fluoroscopic x-ray system |
| Classification Name | System, X-Ray, Fluoroscopic, Image-Intensified |
| Regulation Number | 892.1650 |
| Product Code(s) | JAA, OWB, OXO |

## Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

| Predicate # | Predicate Trade Name (Primary Predicate is listed first) | Product Code |
|---|---|---|
| K200396 | Insight Enhanced™ DRF | JAA |
| K132027 | OEC 9800 Plus | JAA |

## Device Description Summary

21 CFR 807.92(a)(4)

The Insight Enhanced™ DRF is an upgrade package that is designed to be installed on existing fluoroscopic systems, refereed to as host system, to convert the imaging chain from analog to digital. It is comprised of the Insight Enhanced™ DRF Digital Imaging chain and associated interfacing hardware. The Insight Enhanced™ DRF system includes medical grade monitors, computer, and flat panel detector. Interface boards, cabling, and signal converters are included for interfacing with the host system. The x-ray generator and x-ray tube are not modified in any way. A flat panel detector replaces the image intensifier and camera on the base system. All of the fundamental features and principles of operation Insight Enhanced™ DRF are identical to the predicate device, Insight Enhanced (K200369). Both systems are upgrade packages that replace an analog imaging chain with a new digital one. The main components of the product, the PC, software, and detector for the predicate device and for the subject device are identical. Mounting hardware and interfacing components differ to add compatibility to GE OEC 9800/9900 C-arms. Insight Enhanced™ DRF is designed as an upgrade package for General Electric Legacy and P500 fluoroscopy rooms. This submission adds compatibility to a device, the OEC 9800/9900.

## Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Intended for use by a qualified/trained physician or technician for obtaining fluoroscopic and radiographic images of the skull, spinal column, chest, abdomen, and extremities in adult and pediatric patients. Rx only.

## Indications for Use Comparison

21 CFR 807.92(a)(5)

Indications for Use are the same as for the predicate device

## Technological Comparison 21 CFR 807.92(a)(6)

In general, the technological characteristics are similar to the predicate device. The main component i.e. the computer and detector and the Insight DRF software, are the same. The predicate and the subject device use different interface hardware.

## Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Bench testing was conducted using the subject device on the OEC 9800 reference system to evaluate the imaging and dose utilization characteristics compared to the reference OEC 9800 system. The subject device features a 17" x 17" dynamic flat panel detector, in contrast to the 12-inch image intensifier, and utilizes medical-grade flat-panel monitors. Both components provide superior image acquisition and display technology compared to the reference device. Phantom images were collected, including a contrast detail phantom, an anatomic pelvis phantom, and a line-pair penetrometer to compare the image quality and dose utilization between the original and subject devices. These tests demonstrated substantial equivalence to both the predicate device and the OEC 9800 reference system across all magnification modes, pulsed fluoroscopy, continuous fluoroscopy, high-level fluoroscopy, CINE, and single spot image acquisition. These performance tests indicate that the subject device raises no new concerns regarding safety and effectiveness. Therefore, the sponsor believes that the subject device appears to be as safe and effective as the predicate device.