March 6, 2020

Imaging Engineering, LLC
% Mr. George Jachode
President
1318 NW 7th Avenue
CAPE CORAL FL 33993

Re: K200396
Trade/Device Name: Insight Enhanced™ DRF Digital Imaging System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: JAA
Dated: February 12, 2020
Received: February 18, 2020

Dear Mr. 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 (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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200396

Device Name

Insight Enhanced™ DRF Digital Imaging System

Indications for Use *(Describe)*

Intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for obtaining fluoroscopic radiographic images of the skull, spinal column, chest, abdomen, extremities, and other body parts.

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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1. Special 510(k) SUMMARY

Assigned Submission Number: K200396

This summary of Special 510(k) is being submitted in accordance with requirements of SMDA 1990 and 21 CFR Part 807.92.

Date Special 510K summary prepared: February 10, 2020

Submitter's Name: Imaging Engineering, LLC
Submitter's Address: 1318 NW 7th Ave, Cape Coral, Florida 33993
Submitter's Telephone: (239) 223-1371

Contact person: George Jachode/President

Official Correspondent: George Jachode (g.jachode@imagingengineeringllc.com)
Address: 1318 NW 7th Ave, Cape Coral, Florida 33993
Telephone: (239) 223-1371

Name of the device, including the trade or proprietary name if applicable, the common or usual name and the classification name, if known:

510K Number:
Trade/proprietary name: Insight Enhanced™ DRF Digital Imaging System
Model Number: EN-1000-00
Regulation Name: Image-Intensified Fluoroscopic X-ray System
Regulation Number: 21 CFR 892. 1650
Regulatory Class: Class II
Product Code: JAA and LLZ

Predicate Device

Trade Name: Insight Essentials™ DRF Digital Imaging System
510(k) Clearance #: K191310
Clearance date: 06/10/2019
Classification Name: Image Intensified Fluoroscopic X-ray System
Classification Panel: Radiology
CFR Section: 21CFR 892.1650 (Produce Code; JAA and LLZ)
Device Class: Class Ⅱ

2. Device Description

The Insight Enhanced™ DRF Digital Imaging System is designed to provide an additional imaging acquisition device to the existing image intensifier, camera and user interface with a dynamic flat-panel detector (dFPD) on the following FDA approved R&F fluoroscopic imaging systems employing an image intensifier: GE Advantx, GE Legacy, GE P500 and Shimadzu YSF300. The subject fluoro system Insight Enhanced is based on the predicate Insight Essentials. The following dynamic digital detectors are added to the predicate system: Vivix-D 1212G and Vivix-D 1717G. The x-ray generator, beam-limiting device and patient positioner, necessary for a full fluoroscopy system are not part of the subject device. The device software stays unchanged from the predicate Insight Essentials DRF.

The Insight Enhanced™ DRF Digital Imaging System allows the operator to view and enhance high-definition fluoroscopy images. High resolution digital spot images may also be acquired at single or rapid acquisition rates, up to 30 fps. Images may be viewed and enhanced enabling the operator to bring out diagnostic details difficult or impossible to see using conventional imaging techniques. Images can be stored locally for short term storage. The Insight Enhanced™ DRF Digital Imaging System enables the operator to produce hardcopy images with a laser printer or send images over a network for longer-term storage. The major system components include: a fluoroscopic video camera, monitors, and an image processor PC.

3. Indications for Use

Intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for obtaining fluoroscopic radiographic images of the skull, spinal column, chest, abdomen, extremities, and other body parts.

4. Summary of Design Control Risk Management

The Insight Enhanced™ DRF Digital Imaging System has been developed to provide medical professionals optimized workflow when imaging patients while meeting critical functional requirements and international safety standards. The risks and the hazardous impact of the device design were analyzed with FMEA method. The specific risk control and protective measures to mitigate the risks from the device design and production phase were reviewed and implemented in the new product design phase. The overall assessment concluded that all risks and hazardous conditions identified arising from the design and production were successfully mitigated and accepted.

5. Substantial Equivalence

The Insight Enhanced™ DRF Digital Imaging System conforms to the FDA recognized standards as like the predicate device. Based on the recognized standard conformity evidences related to the electro-, mechanical, software-, clinical-and risk management, it's the sponsor's opinion that the subject device is a safe and effective device.

Characteristic	Insight Essentials DRF Digital Imaging System (K191310)	Insight Enhanced DRF Digital Imaging System
Intended Use:	Intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for obtaining fluoroscopic radiographic images of the skull, spinal column, chest, abdomen, extremities, and other body parts.	SAME
Power source	120 VAC 50/60 HZ 2.5 amps	120 VAC 50/60 HZ 2.5 amps
Image acquisition	Up to 15 FPS (spot), up to 30 fps (fluoro)	SAME
File compatibility	DICOM	SAME
Digital Video Source	Basler ACE1920-40gm CMOS camera	VIVIX-D 1212 and VIVIX-D 1717 dFPD
Digital Resolution	1k x 1k 12 bit	SAME
Electrical safety	IEC 60601-1: IEC 60601-1-2 IEC 60601-1-3	SAME

6. Difference Discussion

The dynamic flat-panel detectors Vivix-D1212G and Vivix-D 1717G have been added to the predicate system Insight Essentials in order to provide image acquisition support in addition to the existing CMOS camera.

7. Summary of the technological characteristics of the device compared to the predicate device

Both the subject device and the predicate device have the identical software program that provides a Graphical User Interface (GUI), image processing and patient workflow functions.

Two dFPD detectors have been added to the existing device Insight Essentials, to acquire fluoroscopic and spot images. The dFPDs are both manufactured by the same company Vieworks, use the same manufacturing technology but are of different sizes (12x12 inch and 17x17 inch). The subject device can now be configured with either a CMOS camera or one of the 2 dFPDs.

The VIVIX-D1212 dFPD has already been cleared by the FDA (K180473) for use on a mobile c arm. The Vivix-D 1717 uses the same architecture as the Vivix-D 1212 (K180473) and the only major difference is its larger size. A complete SSXI data report for the VIVIX-D 1717 is provided along with bench test data to establish substantial equivalency.

8. Description of non-clinical tests.

Bench testing was performed on the Vivix digital detectors used with the subject system Insight Enhanced, in order to assess substantial equivalence to the predicate device Insight Essentials. Phantom images were acquired with the subject device and compared to the predicate device, also installed on the same GE Legacy R&F system. These images and the doses used to acquire them were analyzed and compared. In conclusion, the tests obtained demonstrated substantial equivalence to the predicate device.

9. Description of clinical tests.

No clinical data is necessary to evaluate safety or effectiveness for purposes of determining substantial equivalence of the proposed modification. Bench testing was performed to assess the device safety and effectiveness.

10. Conclusion as to Substantial Equivalence.

The Insight Enhanced™ DRF Digital Imaging System, the subject device is substantially equivalent to the predicate (K191310). The intended use, the design principle, and the applicable standards for the subject device are identical to those of the predicate device. The performance test and non-clinical consideration result demonstrate that these differences do not raise any new questions of safety and effectiveness. Therefore, it is the sponsor's opinion that the subject device appears to be as safe and effective as the predicate device.