DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 3, 2016

Ms. Dorai Subramaniam
Regulatory Affairs Leader
283, RUE DE LA MINIERE
BUC, 78530
FRANCE

Re:K122457
Trade/Device Name: GE Innova/Innova IGS/Discovery IGS/Optima angiographic, fluoroscopic X-ray Systems with Cathlab Frontiers solutions
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB, JAA, IZI
Dated: December 12, 2012
Received: December 19, 2012

Dear Ms. Dorai Subramaniam:

This letter corrects our substantially equivalent letter of January 2, 2013.

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert Ochs

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K122457**

Device Name: **GE Innova/Innova IGS/Discovery IGS/Optima angiographic, fluoroscopic X-ray systems with Cathlab Frontiers Solutions**

Indications for Use:

The angiographic X-ray systems are indicated for use for patients from newborn to geriatric in generating fluoroscopic and rotational images of human anatomy for cardiovascular, vascular and non-vascular, diagnostic and interventional procedures.

Additionally, with the OR table, the angiographic X-ray systems are indicated for use in generating fluoroscopic and rotational images of human anatomy for image-guided surgical procedures.

The OR table is suitable for interventional and surgical procedures.

The Cathlab Frontiers solutions are indicated for use in conjunction with single plane and biplane GE angiographic X-ray systems and imaging / data medical devices used in interventional and surgical cathlab environments and cleared for commercial distribution.

The Cathlab Frontiers solutions are integrated GE angiographic X-ray and imaging / data medical devices that simplify the end-to-end clinical workflow in the cathlab by implementing:

(1) communication protocols for exchanging and automatically synchronizing patient, exam, system, and image information between the angiographic X-ray systems and the imaging / data medical devices,

(2) communication protocols for the control of imaging / data medical device functions from the angiographic X-ray systems user interface,

(3) interfaces for displaying the imaging / data medical device output on the monitor display solutions of the GE angiographic X-ray systems.

Prescription Use ___**X**____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Janine M. Morris -S
2013.01.02 17:38:37 -05'00'

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

Section 5: 510(k) Summary

GE Innova/Innova IGS/Discovery IGS/Optima angiographic, fluoroscopic X-ray systems with Cathlab Frontiers solutions

5.1 510(k) Summary 5-2

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	10 August 2012
Submitter:	GE Healthcare GE Medical Systems, SCS 283 rue de la Miniere Buc, FRANCE, 78530 T: +33-01-30-70-42-07
Primary Contact Person:	Dorai Subramaniam Regulatory Affairs Leader GE Healthcare, (GE Medical Systems, SCS) T: +91-80-4088-3769 Email: dorai.subramaniam@ge.com
Secondary Contact Person:	Carol Alloian Regulatory Affairs Leader GE Healthcare –Americas, 9900 W innovation drive Wauwatosa, WI, USA, 53226-4856 T: (847) 244-8327 F: (847) 589-8524 Email: carol.alloian@ge.com
Device: Trade Name:	GE Innova/Innova IGS/Discovery IGS/Optima angiographic, fluoroscopic X-ray systems with Cathlab Frontiers solutions Innova 4100-IQ, Innova 3100-IQ, Innova 2100-IQ, Innova 2121-IQ, Innova 3131-IQ, Innova IGS 540, Innova IGS 530, Innova IGS 520, Innova IGS 620, Innova IGS 630, Discovery IGS 730, Optima CL320i, Optima CL323i.
Common/Usual Name:	Interventional fluoroscopic x-ray system, angiographic x-ray system
Regulation Description:	Image-intensified fluoroscopic x-ray system
Regulation number:	892.1650
Product Code:	OWB, JAA and IZI
Class:	II

Predicate Device(s):	K113034 : GE Innova Solid State X-ray Imager Fluoroscopic X-ray System K111209 : Integrated Innova - S5i System Option K113403 : GE Discovery IGS angiographic, fluoroscopic X-Ray System
Device Description:	The basis for this 510(k) submission is a modification of the family of legally marketed GE angiographic, fluoroscopic X-ray systems devices to expand their indications for use regarding the generic integration interfaces for other imaging / data medical devices used in interventional and surgical cathlab environments and cleared/approved for commercial distribution. Same time with the intended use/indications for use expansion we introduce the Integrated Vivid E9 solution. The Vivid E9 (BT12 version) integrates with Innova IGS 520, Innova IGS 530, and Innova IGS 540 systems, integration consisting in displaying the Vivid E9 system screen on Innova IGS Large Display Monitor solution. For the Innova IGS Vivid E9 integration we apply the specific qualifications criteria and processes described in the section "Determination of Substantial Equivalence" below.
Intended Use:	The angiographic X-ray systems are indicated for use for patients from newborn to geriatric in generating fluoroscopic and rotational images of human anatomy for cardiovascular, vascular and non-vascular, diagnostic and interventional procedures. Additionally, with the OR table, the angiographic X-ray systems are indicated for use in generating fluoroscopic and rotational images of human anatomy for image-guided surgical procedures. The OR table is suitable for interventional and surgical procedures. The Cathlab Frontiers solutions are indicated for use in conjunction with single plane and biplane GE angiographic X-ray systems and imaging / data medical devices used in interventional and surgical Cathlab environments and cleared for commercial distribution. The Cathlab Frontiers solutions are integrated GE angiographic X-ray and imaging / data medical devices that simplify the end-

	to-end clinical workflow in the Cathlab by implementing: (1) communication protocols for exchanging and automatically synchronizing patient, exam, system, and image information between the angiographic X-ray systems and the imaging / data medical devices, (2) communication protocols for the control of imaging / data medical device functions from the angiographic X-ray systems user interface, (3) interfaces for displaying the imaging / data medical device output on the monitor display solutions of the GE angiographic X-ray systems.
Technology:	The GE Angiographic, Fluoroscopic X-ray Systems employs the same Solid State X-ray Imaging and Digital Flat-Panel Detector technology as its predicate devices.
Determination of Substantial Equivalence:	Summary of Non-Clinical Tests: The Integration has been evaluated for electrical and electromagnetic safety. The GE Angiographic, Fluoroscopic X-ray Systems and its applications and accessories comply with voluntary standards and applicable performance standards for radiation emitting products of this premarket submission. The following quality assurance measures were applied to the development of the system: • Risk Analysis • Requirements Reviews • Design Reviews • Testing on unit level (Module verification) • Integration testing (System verification) • Performance testing (Verification) • Safety testing (Verification) • Simulated use testing (Validation) Summary of specific qualification of 3rd party systems integrations: The criteria to qualify the integration of 3rd party imaging/data medical devices are based on the following aspects: • Shall be "FDA cleared/approved device" • Shall comply with one or more generic integration interfaces offered by the GE angiographic, fluoroscopic X-ray systems.

	• Integration of devices shall be safe and effective and shall not raise different questions of safety and effectiveness than the predicate device(s). Summary of Clinical Tests: The subject of this premarket submission, Innova/Innova IGS/Discovery IGS/Optima angiographic, fluoroscopic X-ray Systems with Cathlab Frontiers solutions, did not require clinical studies to support substantial equivalence as one of the criteria for integration rely on the fact that they are already cleared /approved devices by FDA. Integration does not introduce any new clinical information and the clinical information is pre-existing on the cleared or approved devices.
Conclusion:	GE Healthcare considers the GE Innova/Innova IGS/Discovery IGS/Optima angiographic, fluoroscopic X-ray systems with Cathlab Frontiers solutions to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).