510(k) Summary

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

Date Summary was revised:	March 4th , 2014
Submitter:	GE Healthcare GE MEDICAL SYSTEMS, SCS 283 RUE DE LA MINIERE 78530 BUC – FRANCE T: +33-(0)1-30-70-47-41
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Secondary Contact Person:	Hubert Welsch Regulatory Affairs Leader, GE Healthcare 283 RUE DE LA MINIERE 78530 BUC – FRANCE T: +33-(0)1-30-70-49-51 Email: hubert.welsch@ge.com
Device/Trade Name:	Discovery IGS 740
Common/Usual Name:	interventional fluoroscopic x-ray system, angiographic x-ray system
Regulation Description: Regulation number: Product Code: Class:	Image-intensified fluoroscopic x-ray system. 892.1650 OWB, JAA and IZI II
Predicate Device(s):	K122457: Innova/Innova IGS/Discovery IGS/Optima angiographic, fluoroscopic X-ray Systems with Cathlab Frontiers solutions.
Device Description:	The proposed device, Discovery IGS 740 is an interventional fluoroscopic x-ray system/ x-ray angiographic system with a 41 cm square digital detector. Discovery IGS 740 is a new product model of the GE Discovery IGS interventional fluoroscopic x-ray system/ x-ray angiographic system

	platform with a 41cm square digital detector. GE Discovery IGS x-ray angiographic systems are based on the GE laser guided gantry. The 41cm square digital detector of the cleared predicate device Innova IGS 540 K122457 is mounted on the GE Discovery IGS gantry. This gantry is the same gantry as the Discovery IGS 730 predicate device, originally cleared with K113403. Discovery IGS 740 is proposed in an Interventional configuration and in an OR configuration (with OR table) for the indications for use of surgery. Discovery IGS 740 has no additional indications for use compared with the predicate device Innova/Innova IGS/Discovery IGS/Optima angiographic, fluoroscopic X-ray Systems with Cathlab Frontiers solutions K122457.
Intended Use 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.
Technology:	The proposed Discovery IGS 740 is a new combination of the laser guided mobile AGV gantry of the Discovery IGS 730 (K113403) and of the 41cm solid state detector of the Innova IGS 540 (K122457). This new combination is the most important difference. It impacts the collision avoidance system which has been adapted for the 41cm detector. This adaptation does not impact the safety and effectiveness of the proposed device established with the predicate devices (K113403 & K122457).
Determination of Substantial Equivalence:	Discovery IGS 740 complies with the voluntary and mandatory standards listed in Table 1. Summary of Non-Clinical Tests: • Simulated Use Testing ensures the system conforms to user needs and intended uses through simulated clinical workflow using step-by step procedures that would be performed for representative clinical applications.

	• Usability validation testing is conducted to confirm that the product can be used safely and effectively. The participants for these tests are licensed and/or clinically trained healthcare providers or users. • Product verification ensures the system conforms to its requirements including hazard mitigations risk management requirements. The verification tests confirm that design output meets design input requirements. Tests are executed at component, software subsystems and system levels. Dose verification, image quality verification and functional testing are part of system level verification. Performance imaging of Innova CT (CA-CBCT) has been confirmed with bench testing for uniformity, contrast and detail imaging performances. • Software reliability is verified through intensive cycling of the system. The cycling tests use scenarios that simulate clinical workflow that would be performed for representative clinical applications. • Safety testing is performed to confirm that the product meets the requirements of the standards listed in Table 1. The Non-clinical Testing confirms Discovery IGS 740 meets the user requirements and its intended use and meets the design inputs requirements. <u>Summary of Clinical Tests:</u> The subject of this premarket submission, Discovery IGS 740, did not require clinical studies to support substantial equivalence. It does not introduce new indications for use. Substantial equivalence relies on clinical information that is pre-existing on the cleared predicate device (K023178).
<u>Conclusion:</u>	GE Healthcare considers the Discovery IGS 740 to be as safe and effective as its predicate devices, and its performances to be substantially equivalent to the predicate device(s).

Table 1

Standards N°	Standards organization	Standards Title	Version	Date
21 CFR 1020.30-32	FDA	FDA Federal Performance Standard	2013	2013
60601-1	IEC	Medical Electrical Equipment –General requirements for basic safety and essential performance	Ed 3	2005
60601-2-43	IEC	Medical Electrical Equipment – Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures (2nd edition	Ed 2	2010
60601-1-2	IEC	Medical Electrical Equipment – Part -1-2: General requirements for safety – Collateral standard: Electromagnetic Compatibility – Requirements and tests	Ed 3	2007
60601-1-3	IEC	Medical Electrical Equipment – Part -1: General requirements for safety, Section 1.3 Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment	Ed 2	2008
60601-1-6	IEC	Medical electrical equipment –Part 1-6: General requirements for basic safety and essential performance –Collateral standard : Usability	Ed 3 ,	2010
IEC60601-2-46 (for the table)	IEC	Medical electrical equipment , Part2-46: Particular requirements for the safety of operating tables	Ed 2	2010

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

April 24, 2014

GE Medical Systems Scs
Michel Genuer
283 Rue De La Miniere
Buc, 78530 FRANCE

Re: K133278
Trade/Device Name: Discovery IGS 740
Regulation Number: 21 CFR 192.1650
Regulation Name: Interventional Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB
Dated: April 14, 2014
Received: April 16, 2014

Dear Michel Genuer:

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.

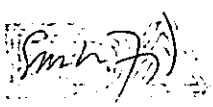
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 Small Manufacturers, International and Consumer Assistance 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" (21 CFR 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 Small Manufacturers, International and Consumer Assistance 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,



for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133278

Device Name
Discovery IGS 740

Indications for Use *(Describe)*
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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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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Department of Health and Human Services
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Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."