GE Healthcare
Michel Genuer
Senior Regulatory Affairs Program Manager
283 Rue De La Miniere
78530 Buc, France

November 2, 2018

Re: K181403
Trade/Device Name: Innova IGS 5, Innova IGS 6, Discovery IGS 7, Discovery IGS 7 OR
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Codes: OWB, JAA, IZI, OXO
Dated: May 17, 2018
Received: May 29, 2018

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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert A. Ochs, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181403

Device Name
Innova™ IGS 5, Innova™ IGS 6, Discovery™ IGS 7, Discovery™ IGS 7 OR

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

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

Date:	31-October-2018
Submitter:	GE MEDICAL SYSTEMS SCS 283 RUE DE LA MINIERE 78530 BUC, FRANCE
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Device Trade Name:	**Innova™ IGS 5, Innova™ IGS 6, Discovery™ IGS 7, Discovery™ IGS 7 OR**
Common/Usual Name:	interventional fluoroscopic x-ray system, angiographic x-ray system
Regulation description:	Image-intensified fluoroscopic x-ray system
Regulation Number:	21CFR 892.1650
Product Code:	OWB
Subsequent Product Codes	JAA, IZI and OXO for Discovery™ IGS 7 and Discovery™ IGS 7 OR.
Classification:	Class II

Predicate Device(s):	Trade Name:	*GE Innova/Innova IGS/Discovery IGS/Optima angiographic, fluoroscopic X-ray systems with Cathlab Frontiers solutions.*
	510(k) Clearance:	K122457
	Regulation Name:	Image-Intensified fluoroscopic x-ray system
	Regulation Number:	21CFR 892.1650
	Classification:	Class II
	Product Code:	Primary product code: OWB Secondary Product codes: IZI, JAA
	Trade Name:	*Discovery IGS™ 740*
	510(k) Clearance:	K133278
	Regulation Name:	Image-Intensified fluoroscopic x-ray system
	Regulation Number:	21CFR 892.1650
	Classification:	Class II
	Product Code:	Primary product code: OWB Secondary Product codes: JAA, OXO
Device Description:	GE Healthcare IGS interventional x-ray systems are designed to perform monoplane, biplane fluoroscopic x-ray examinations to provide the imaging information needed to perform minimally invasive interventional X-Ray imaging procedures (standard configuration). Additionally, in the OR configuration (with an OR Table), these systems allow to perform surgery and X-Ray image guided surgical procedures in a hybrid Operating Room. Discovery™ IGS 7 OR, Discovery™ IGS 7, Innova™ IGS 6, Innova™ IGS 5 are the GE Healthcare IGS interventional X-Ray system product models. Each product model is designed with a set of components that are combined into different configurations for providing specialized interventional x-ray systems. GE Healthcare IGS interventional x-ray system consists of a C-arm positioner (monoplane or biplane), an x-ray imaging table or the interface to the radiologic table, an x-ray tube assembly (per plane), an x-ray power unit with its exposure control unit (per plane), an x-ray imaging chain (including a digital detector and an image processing unit, per plane). Discovery™ IGS 7 is a monoplane system (C-arm with mobile AGV gantry) and is proposed in IGS 740 configuration with a square 41cm digital detector or in IGS 730 configuration with a square 31cm digital detector. These product configurations are declined in sub configurations: Standard or OR configuration. The Innova-IQ table in the OR configuration is the GE OR table.	

	Discovery™ IGS 7 OR is a monoplane system (C-arm positioner with mobile AGV gantry) and is proposed with a square 41cm digital detector or with a square 31cm digital detector configuration. This is the product model compatible with a qualified configuration of the Maquet Magnus OR table system. This product model is provided with a table integration kit. The Magnus OR table configuration compatible with Discovery™ IGS 7 OR includes a flat table top configuration for Interventional X-Ray imaging and surgery procedures, an optional universal table top (table top with articulated joints) to enable expansion to surgical procedures requiring advanced patient positioning and with X-Ray imaging capabilities. A set of Magnus OR table accessories is included in the compatible configuration. Innova™ IGS 6 is a biplane system (a dual C-arm positioner, LC and LP gantry) and is provided with an Omega V table. Innova™ IGS 6 is proposed in IGS 630 configuration with a square 31cm digital detector per plane or in IGS 620 configuration with a square 20.5cm digital detector per plane. These product configurations are available in Standard configuration. Innova™ IGS 5 is a monoplane system (C-arm positioner with LC gantry) and is proposed with a square digital detector of 41cm or 31cm or 20.5cm. These product configurations are available in Standard configuration with Innova-IQ or Omega V table or Omega IV table (IGS 520 configuration only); or in OR configuration with GE OR table. The purpose of this Premarket Notification is for 2 changes: First, a change of the collision management of Discovery™ IGS 7 OR to enable the use of a Neurosurgical head holder (skull clamp). During trauma neck surgery and stereotactic navigation, a gantry collision with the skull clamp could result in patient harm, delayed or halted surgical procedures. The subject of this submission is to introduce a functionality for adapting the collision avoidance model to the geometrical characteristic of the skull clamp and patient position with a guard volume defined and validated by the operator during the procedure preparation phase. During the procedure, the collision avoidance software will slow down and stop gantry and/or table axis to minimize risk of collision of a motorized moving part with the patient head or the skull clamp. In this configuration, the OR table, the Neurosurgical head holder and its support are from third party Medical device manufacturers. As a consequence, there is no mechanical interfaces between these devices and the Discovery™ 7 OR. Those devices are registered and cleared in the US. The Neurosurgical head holder is from Pro Med Instrument manufacturer (K063494). The OR table is the registered Magnus OR table system from Maquet manufacturer.

	The second change is for a primary technology change, adding an optional wireless footswitch in the examination room to Innova™ IGS 5, Innova™ IGS 6, Discovery™ IGS 7 and Discovery™ IGS 7 OR. It provides identical functionalities as the wired footswitch for the control of X-ray on and off, and for the control of the table top brake release. Labelling is updated for the enhanced collision management for the use with Neurosurgical head holder and for the wireless footswitch.
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.
Indication 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 modified GE Healthcare IGS Interventional X-Ray systems employ the same fundamental scientific technology as the unmodified predicate devices. The change to enable the dynamic adaptation of the collision avoidance model with a model fitted to the needs of the operator and of the procedure, is a software change. The collision avoidance software is the same as with the predicate devices. The change is the dynamic adaptation of the collision avoidance model. All causes of hazard relative to the use of a Neurosurgical head holder in combination with the Discovery™ IGS 7 OR have been identified and mitigated. The optional wireless footswitch consists of a footswitch containing a transmitter system, a receiver that is installed near the connection plug of the wired footswitch (at the table base of the Innova-IQ table, of the Omega table or at the Discovery Control Center table side cart), and a charger. The introduction of this wireless footswitch does not change existing electrical or software interface of the predicate devices. The new option is equivalent to the wired footswitch on the predicate in that the functionalities are identical. The communication between the footswitch emitter and the

	receiver is performed via a proprietary protocol using 2.4 GHz radio frequency technology. The wireless option provides placement flexibility and reduces cable clutter. Both changes have no impact on x-ray imaging performance. The intended use and indications for use remain unchanged from those of the predicate devices. The expansion to x-ray interventional, minimally invasive surgery and conventional open surgery procedures requiring the use of a neurosurgical holder in combination with Discovery™ IGS 7 OR is included in Discovery IGS 7 OR's indications for use of interventional, image-guided surgical and surgical procedures.
Determination of Substantial Equivalence:	The modifications to Discovery™ IGS 7 OR collision management software and to IGS interventional x-ray systems for the wireless footswitch were developed under the GE Healthcare's design controls processes and overall quality management system. IGS interventional x-ray systems conform to 21CFR 1020.30 and 32, and with voluntary standards IEC 60601-2-43:2010, IEC 62304 (2006) and IEC 62366 (2007). Risk management activities using risk analysis to identify any potential issues incorporating the wireless footswitch and the use of a skull clamp were performed. These issues were assessed and mitigated. The following testing was used to assess safety and effectiveness and, thus, to establish the substantial equivalence with the predicate devices. <u>Summary of Non-Clinical Tests:</u> The following quality management measures were applied to the development of these modifications: • Simulated Use Testing ensured 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 was conducted to confirm that the product can be used safely and effectively. Participants were representatives of actual users, with knowledge of the customer needs and clinical applications. • Product verification ensured the system conforms to its requirements including hazard mitigations risk management requirements. The verification tests confirmed that design output meet design input requirements. Tests were executed at component, software subsystems and system levels.

	• Safety testing were performed to confirm that the product meets the requirements of the aforementioned standards. It includes the EMC and coexistence testing per the **"**Radio Frequency Wireless Technology in Medical Devices" Guidance for Industry and Food and Drug Administration Staff issued on August 14, 2013 (Wireless Guidance). <u>Summary of Clinical Tests:</u> The subject of this premarket submission, change to Discovery™ IGS 7 OR collision management to enable the use of a neurosurgical head holder and the change to add an optional wireless footswitch in the examination room to GE Healthcare interventional x-ray systems did not require clinical studies to support substantial equivalence. The expansion to x-ray and surgical procedures requiring the use of a neurosurgical holder in combination with Discovery™ IGS 7 OR is included in Discovery IGS 7 OR's indications for use of image-guided surgical and surgical procedures. It does not introduce new indications for use. Substantial equivalence relies on clinical information that is pre-existing on the cleared predicate devices. Design verification and validation testing were performed to confirm that the safety and effectiveness of the devices has not been affected. The test plans and results have been executed with acceptable results.
Conclusion:	GE Healthcare considers that the Discovery™ IGS 7 OR incorporating the enhanced collision management for the use of a skull clamp or that a GE Healthcare IGS interventional x-ray system incorporating the optional wireless footswitch to be as safe and as effective and substantially equivalent to the predicate devices. This conclusion is based on the fact that Discovery™ IGS 7 OR incorporating the collision management optimization for the use in combination with the Neurosurgical head holder and that GE Healthcare interventional x-ray systems incorporating the optional wireless footswitch have: • the same indications for use as their predicate devices. • The modified devices have the same technological characteristics as their predicate devices. • Verification and Validation testing has demonstrated that the design inputs, user requirements, and risk mitigations have been met. • Engineering bench testing per the FDA guidance Radio frequency wireless technology in medical devices as well as conformance to IEC standards and guidance documents were provided.

	• The successful completion of the above testing was sufficient to assess safety and effectiveness and, thus, to establish the substantial equivalence.