October 11, 2023

GE Medical Systems SCS
% Hubert Welsch
Associate Regulatory Affairs Program Manager
283 Rue De La Miniere
Buc, 78530
FRANCE

Re: K232344
Trade/Device Name: Allia IGS 3, Allia IGS 5, Allia IGS 7, Allia IGS 7 OR
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB, JAA, IZI and OXO
Dated: September 14, 2023
Received: September 15, 2023

Dear Hubert Welsch:

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.

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 Radiological 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232344

Device Name
Allia IGS 3, Allia IGS 5, Allia IGS 7, Allia 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:	27-September-2023
Submitter:	GE MEDICAL SYSTEMS SCS 283 RUE DE LA MINIERE 78530 BUC, FRANCE
Primary Contact Person:	Hubert WELSCH Associate Regulatory Affairs Program Manager GE HealthCare (GE MEDICAL SYSTEMS SCS) Tel: (+33)-1-3070-3847 Email: hubert.welsch@ge.com
Secondary Contact Person:	Michelle HUETTNER Regulatory Affairs Director IGT and Oncology GE HealthCare Tel: +1 (901) 558-8035 Email: michelle.huettner@ge.com
Device Trade Name:	Allia IGS 3, Allia IGS 5, Allia IGS 7, Allia 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:	21 CFR 892.1650
Product Code:	OWB
Subsequent Product Codes	JAA, IZI; and OXO for Allia IGS 7 and Allia IGS 7 OR.
Classification:	Class II

Predicate Device(s):	K181403: Innova IGS 5, 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: 21 CFR 892.1650 Product Code: OWB Subsequent Product Codes: JAA, IZI; and OXO for Discovery IGS 7 and 7 OR. Classification: II

Device Description:	GE HealthCare IGS interventional x-ray systems are designed to perform monoplane 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. Allia IGS 3, Allia IGS 5, Allia IGS 7, Allia IGS 7 OR are monoplane 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, an x-ray table or the interface to the radiologic table, an x-ray tube assembly, an x-ray power unit with its exposure control unit, an x-ray imaging chain (including a digital detector and an image processing unit). Allia IGS 5 is a monoplane system (C-arm positioner with L-shaped gantry) and is proposed in IGS 530 configuration with a square digital detector of 31cm (also called 30 cm configuration) or in IGS 520 configuration with a square digital detector of 20.5cm (also called 20 cm configuration). These product configurations are available in Standard configuration with Omega V table or Omega IV table (IGS 520 configuration only); or in OR configuration with Innova-IQ GE HealthCare OR table. Allia IGS 3 is a monoplane system (C-arm positioner with L-shaped gantry) and is proposed with a square digital detector of 31cm. This product is available in Standard configuration with Omega V table. Allia IGS 7 is a monoplane system (C-arm with mobile AGV gantry) and is proposed in IGS 730 configuration with a square 31cm digital detector (also called 30 cm configuration). This product configuration is described in sub configurations: Standard or OR configuration. The Innova-IQ table in the OR configuration is the GE HealthCare OR table. Allia IGS 7 OR is a monoplane system (C-arm positioner with mobile AGV gantry) and is proposed in IGS 730 OR configuration 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 Allia IGS 7 OR includes flat table top configurations 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. The purpose of this Premarket Notification is for the re-design of the x-ray source assembly. Allia IGS 3, Allia IGS 5 in IGS 520 and IGS 530 configurations, Allia IGS 7 in IGS 730 configuration, and Allia IGS 7 OR in IGS 730 OR configuration will be improved and will be marketed as Allia IGS 3 Pulse, Allia IGS 5 Pulse, Allia IGS 7 Pulse, and Allia IGS 7 OR Pulse. All these four models may also be designated with the marketing name Allia IGS Pulse.
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 nonvascular, 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 intended use and indications for use are unchanged from the predicate device.

Technology:

The modified GE HealthCare Allia IGS Interventional x-ray systems employ the same fundamental scientific technology as the unmodified predicate devices. The Solid State x-ray Imaging Devices (digital detectors) stay unchanged. The table below summarizes the substantive feature/technological differences between the predicate device and the subject device:

Subsystem	**Innova IGS 5, in IGS 520 and IGS 530 configurations Discovery IGS 7 in IGS 730 configuration Discovery IGS 7 OR in IGS 730 OR configuration (Predicate Devices, K181403)**		**Allia IGS 3, Allia IGS 5, Allia IGS 7, Allia IGS 7 OR (Proposed Devices)**
x-ray tube	Performix 160A - Bi-filament cathode - 0.3, 0.6, 1.0 focal spot sizes - Ball bearing		Performix Pulsar - Tri-filament cathode - 0.3, 0.5, 0.8 focal spot sizes - Liquid Metal rotor bearing
Tube cooling unit	Closed-loop remote water chiller		Closed-loop remote oil cooler
High-voltage generator	Jedi 100 VASC 1T Peak power: 100 kW		Gaia Peak power: 100 kW
Collimation	CARD AMP 20 cm config 2 pairs of collimation blades. 0.1, 0.2, 0.3, 0.6 and 0.9 mm of copper Spectral filtration. 1 integrated contour filter blades.	AF DSA 01 30 cm config 2 pairs of collimation blades. 0.1, 0.2, 0.3 mm of copper Spectral filtration. 3 integrated contour filter blades.	MFD 2 pairs of collimation blades. 0.1, 0.2, 0.3, 0.6 and 0.9 mm of copper Spectral filtration 1 integrated contour filter blades.

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<tr><td>Solid state digital detector</td><td>-Model NGB20 in 20cm Configuration
-Model Dynamic 31 in 30cm Configuration, accompanied by a detector conditioner and removable anti-scatter grids</td><td>No change. Identical.</td></tr>
<tr><td>Standards</td><td>IEC 60601-1 Ed. 3.0
IEC 60601-1-2 Ed 4.0
IEC 60601-1-3 Ed 2.0
IEC 60601-2-28 Ed 2.0
IEC 60601-2-43 Ed. 2.0
NEMA XR-27</td><td>IEC 60601-1 Ed. 3.1
IEC 60601-1-2 Ed 4.0
IEC 60601-1-3 Ed 2.1
IEC 60601-2-28 Ed 3.0
IEC 60601-2-43 Ed. 2.2
NEMA XR-27</td></tr>
</table>

The changes described above do not change the fundamental control mechanism, operating principle, energy type, and do not change the intended use from the predicate devices.</td></tr>
<tr><td>Determination of Substantial Equivalence:</td><td>The Allia IGS 3, Allia IGS 5, Allia IGS 7, Allia IGS 7 OR has completed testing and is in compliance with IEC60601-1 Ed. 3.1 (FDA Recognition #19-4) and its associated collateral and particular standards, 21 CFR Subchapter J, and NEMA standard XR-27. The devices have successfully completed all applicable testing underthe GE HealthCare quality system and design control. They were designed and are manufactured under the Quality System Regulations of 21 CFR 820 and ISO 13485. The following quality assurance measures were applied to the development of the system:
• Risk Analysis
• Required Reviews
• Design Reviews
• Testing on unit level (Module verification)
• Integration testing (System verification)
• Performance testing (Verification)
• Safety testing (Verification)
• Simulated use testing (Validation)

The following FDA guidance documents were utilized in the development of the devices:
• Electromagnetic Compatibility (EMC) of Medical Devices (06-Jun-2022)
• Off-The-Shelf Software Use in Medical Devices (FDA, 27-Sep-2019)
• Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software (14-Jan-2005)
• Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (02-Oct-2014)</td></tr>
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	• Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (11-May-2005) • Policy Clarification for Certain Fluoroscopic Equipment Requirements (FDA, 08-May-2019) • Pediatric Information for X-ray Imaging Device Premarket Notifications (28-Nov-2017) GE HealthCare believes the Allia IGS 3, Allia IGS 5, Allia IGS 7, Allia IGS 7 OR systems are of comparable type and substantially equivalent to the cleared predicate systems Innova IGS 5, Discovery IGS 7, Discovery IGS 7 OR (K181403). The substantial equivalence was also based on software documentation for a "Moderate" level of concern device. <u>Summary of Additional Testing:</u> ***Non-Clinical Testing:*** The verification and validation testing have been successfully completed as required by design control procedures under GE HealthCare's quality system. This includes risk management, software verification and validation testing as well as image quality and dose performance using standard IQ metrics and QA phantoms. Additional engineering bench testing was performed to substantiate the quantitative performance claims related to the new x-ray source assembly. Additionally, testing was performed to demonstrate the overall imaging performance of Allia IGS 3, Allia IGS 5, Allia IGS 7, Allia IGS 7 OR systems using a wide variety of anthropomorphic phantoms. ***Clinical Testing:*** The Allia IGS 3, Allia IGS 5, Allia IGS 7, Allia IGS 7 OR systems can be fully tested on the engineering bench thus no additional clinical testing was required to support substantial equivalence.
Conclusion:	Based on the conformance to standards, development under the GE HealthCare quality system, and the engineering testing provided, GE HealthCare believes that the Allia IGS 3, Allia IGS 5, Allia IGS 7, Allia IGS 7 OR are as safe and effective, and perform in a substantially equivalent manner to the predicate devices Innova IGS 5, Discovery IGS 7, Discovery IGS 7 OR (K181403).