December 9, 2025

GE Medical Systems SCS
% Bessou Anne
Senior Regulatory Affairs Manager
283, rue de la Miniere
BUC, 78530
FRANCE

Re: K251199
Trade/Device Name: Allia Moveo
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, JAA, IZI, OXO
Dated: May 23, 2025
Received: November 13, 2025

Dear Bessou Anne:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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 Radiologic 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)*
K251199

Device Name
Allia Moveo

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

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

Date:	November 18th, 2025
Submitter:	GE Medical Systems SCS Establishment Registration Number - 611343 283, rue de la Minière 78530 Buc, France
Primary Contact Person:	Anne Bessou Senior Regulatory Affairs Manager GE HealthCare, (GE Medical Systems SCS) Tel: +33159032132 Email: anne.bessou@gehealthcare.com
Secondary Contact Person:	Michelle Huettner Regulatory Affairs Director Tel: +1 901 558 8035 Email: michelle.huettner@gehealthcare.com
Device Trade Name:	Allia Moveo
Common/Usual Name:	Interventional fluoroscopic x-ray system, angiographic x-ray system
Regulation number: Regulation description:	21 CFR 892.1650 Image-intensified fluoroscopic x-ray system
Product Code:	OWB
Subsequent Product Codes:	JAA, IZI, OXO
Classification:	Class II

Predicate Device:	K232344: Allia IGS 7 Common name: Interventional fluoroscopic x-ray system, angiographic x-ray system Regulation: 21 CFR 892.1650- Image intensified fluoroscopic x-ray system Product Code: OWB Subsequent Product Codes: IZI, JAA, OXO Classification: Class II
Reference Device(s):	K181403: Discovery IGS 7 K243446: 3DXR

Device Description:

GE HealthCare 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. Additionally, with an OR table, these systems allow to perform surgery and X-Ray image guided surgical procedures in a hybrid Operating Room.

Allia™ Moveo is a GE HealthCare interventional X-Ray system product model. It consists of a C-arm positioner, an X-ray 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™ Moveo is a monoplane system (C-arm with mobile AGV gantry), with a square 41cm digital detector and the Innova^{IQ} table (with an option to make it an OR table).

Allia™ Moveo is an image acquisition system requiring connection to the GE HealthCare Advantage Workstation (AW) for 3D reconstruction. When a 3D acquisition is performed on the Allia™ Moveo system, the acquired 2D images are transferred to the Advantage Workstation (AW) to be processed by 3DXR (reference device K243446) for 3D reconstruction.

The purpose of this Premarket Notification is the introduction of a new C-arm with a modified detector mount.

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.

Technological characteristics:

The Allia Moveo employs the same fundamental scientific technology, basic design, construction, materials, energy source, control mechanism, and operating principles as the predicate device. The table below summarizes the substantive feature/technological differences between the predicate device and the subject device:

Specification	**Proposed device Allia Moveo**	**Predicate device K232344 Allia IGS 7 in IGS 730 configuration**	**Reference device K181403 Discovery IGS 7 in IGS 740 configuration**
Detector	41x41 cm detector	31x31 cm detector	41x41 cm detector
Collimator	LFD • Spectral filtration: 0.1, 0.2, 0.3, 0.6 and 0.9 mm of copper • 3 integrated contour filter blades	MFD: • Spectral filtration: 0.1, 0.2, 0.3, 0.6 and 0.9 mm of copper • 1 integrated contour filter blade	AF DSA 01 • Spectral filtration: 0.1, 0.2, 0.3, mm of copper • 3 integrated contour filter blades
X-ray Tube	Performix™ Pulsar		Performix™ 160A
X-Ray Generator	100 kW high-frequency Gaia three-phase power unit		100 kW Jedi 100 VASC 1T high-frequency three-phase power unit
Gantry	New C-arm mounted on a laser-guided motorized vehicle rolling on the floor.	Offset C-arm mounted on a laser-guided motorized vehicle rolling on the floor.	
3D acquisition	With the gantry at the head, left or right of the table	With the gantry at the head of the table	
Standards	IEC 60601-1:2005+A1:2012+A2:2020 IEC 60601-1-2:2014+A1:2020 IEC 60601-1-3:2008+A1:2013+A2:2021 IEC 60601-2-43:2022 IEC 60601-2-46:2023 NEMA XR-27	IEC 60601-1:2005+A1:2012+C1:2014 IEC 60601-1-2:2014 IEC 60601-1-3:2008+A1:2013 IEC 60601-2-43:2010+A1:2017+A2:2019 IEC 60601-2-46:2016 NEMA XR-27	IEC 60601-1:2005 IEC 60601-1-2:2014 IEC 60601-1-3:2008, IEC 60601-2-43:2010 IEC 60601-2-46:2016 NEMA XR-27

Specification	Proposed device Allia Moveo	Predicate device K232344 Allia IGS 7 in IGS 730 configuration	Reference device K181403 Discovery IGS 7 in IGS 740 configuration
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 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 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 changes described above do not change the intended use or indications for use from the predicate device or reference device. The indications for use for the proposed subject device are the same as the indications for use for the cleared predicate device.

The device's technological characteristics do not raise new questions of safety or effectiveness.

Determination of Substantial Equivalence:

<u>Summary of Non-Clinical Tests:</u>

The Allia Moveo has completed testing and is in compliance with IEC 60601-2-43:2022 (FDA recognition #12-351), 21 CFR Subchapter J, and NEMA standard XR-27.

It has successfully completed all applicable testing under the 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)

Summary of additional testing:

Non-Clinical Testing: Additional engineering bench testing was performed to substantiate the quantitative performance claims related to the new gantry using a wide variety of anthropomorphic phantoms.

Comprehensive 3D imaging performance testing was conducted to demonstrate equivalent performance with the gantry at the head, left or right position.

3D clinical images were evaluated for image quality by a US board-certified radiologist and found to be acceptable.

FDA Guidance Documents applied:

- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (June 2025)
- Content of Premarket Submissions for Device Software Functions (June 2023)
- Premarket Assessment of Pediatric Medical Devices (March 2014)
- Pediatric Information for X-ray Imaging Device Premarket Notifications Guidance for Industry and Food and Drug Administration Staff Document (November 28, 2017)

Conclusion:

Based on the conformance to standards, development under the GE HealthCare quality system, and the engineering testing provided, GE HealthCare considers that the Allia™ Moveo is as safe, as effective, and performance is substantially equivalent to the predicate device.