GE Medical Systems SCS
℅ Ning Wen
Regulatory Affairs Program Manager Associate
283, rue de la Miniere
Buc, 78530
FRANCE

March 21, 2023

Re: K223490
Trade/Device Name: FlightPlan for Embolization
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: February 22, 2023
Received: February 22, 2023

Dear Ning Wen:

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 and Part 809); 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/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 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 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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software 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)*
K223490

Device Name

FlightPlan for Embolization

Indications for Use *(Describe)*

FlightPlan for Embolization is a post processing software package that helps the analysis of 3D X-ray angiography images. Its output is intended to be used by physicians as an adjunct means to help visualize vasculature during the planning phase of embolization procedures. FlightPlan for Embolization is not intended to be used during therapy delivery.

The output includes segmented vasculature, and selective display of proximal vessel and distal vessels from a reference point determined by the user. User-defined data from the 3D X-ray angiography images may be exported for use during the guidance phase of the procedure. The injection points should be confirmed independently of FlightPlan for Embolization prior to therapy delivery.

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.

510(k) Summary of Safety and Effectiveness

K223490

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

Date:	March 20, 2023
Submitter:	GE Medical Systems SCS Establishment Registration Number - 9611343 283, rue de la Minière 78530 Buc, France
Primary Contact:	Ning WEN Regulatory Affairs Program Manager Associate GE HealthCare, (GE Medical Systems SCS) Tel: +33 6 2324 6023 Email: ning.wen@ge.com
Secondary Contact	Rachel Schandel Senior Regulatory Affairs Leader Tel: +1 385 237 7519 Email: rachel.schandel@ge.com
Device Trade Name:	**FlightPlan for Embolization**
Common/Usual Name:	FlightPlan for Embolization, with AI Segmentation option
Regulation Number:	21CFR 892.2050, Medical image management and processing system
Product Code:	QIH
Regulatory Class:	Class II
Predicate Device:	
Device Name:	FlightPlan for Embolization
Manufacturer:	GE Medical Systems SCS
510(k) number:	K193261
Regulation Number:	21CFR 892.2050, Medical image management and processing system
Product Code:	LLZ
Regulatory Class:	Class II

Device Description and Marketed Devices:

FlightPlan for Embolization is a post-processing, software-only application using 3D X-ray angiography images (CBCT) as input. It helps clinicians visualize vasculature to aid in the planning of endovascular embolization procedures throughout the body.

A new option, called **AI Segmentation**, was developed from the modifications to the predicate device, GE HealthCare's FlightPlan for Embolization [K193261]. It includes two new algorithms. This AI Segmentation option is what triggered this 510(k) submission.

The software process 3D X-ray angiography images (CBCT) acquired from GE HealthCare's interventional X-ray system [K181403], operates on GEHC's Advantage Workstation (AW) [K110834] platform and AW Server (AWS) [K081985] platform, and is an extension to the GE HealthCare's Volume Viewer application [K041521].

FlightPlan for Embolization is intended to be used during the planning phase of embolization procedures. These procedures workflows are split into 5 main phases:

(1) Planning, using DSA and CBCT to characterize the anatomy and identify injection point candidates.
(2) Navigation, to position catheters under fluoroscopic guidance.
(3) Decision, to confirm treatment point(s) using DSA and Selective CBCT.
(4) Treatment, which consists into injection of embolization material from the confirmed treatment point(s).
(5) Assessment, to assess the embolization procedure end-point.

The proposed device is only used as part of the phase (1) Planning.

The primary features/functions of the proposed software are:

- Semi-automatic segmentation of vasculature from a starting point determined by the user, when AI Segmentation option is not activated;
- Automatic segmentation of vasculature powered by a deep-learning algorithm, when AI Segmentation option is activated;
- Automatic definition of the root point powered by a deep-learning algorithm, when AI Segmentation option is activated;
- Selective display (Live Tracking) of proximal vessel and distal vessels from a point determined by the user's cursor;
- Ability to segment part of the selected vasculature;
- Ability to mark points of interest (POI) to store cursor position(s);
- Save results and optionally export them to other applications such as GEHC's Vision Applications [K092639] for 3D road-mapping.

Intended Use:

FlightPlan for Embolization is a post processing software package that helps the analysis of 3D X-ray angiography images. Its output is intended to be used by physicians as an adjunct means to help visualize vasculature.

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The output includes segmented vasculature, and selective display of proximal vessel and distal vessels from a reference point determined by the user. User-defined data from the 3D X-ray angiography images may be exported for use during the guidance phase of the procedure. The injection points should be confirmed independently of FlightPlan for Embolization prior to therapy delivery.

Technology:

The proposed device FlightPlan for Embolization employs the same fundamental scientific technology as its predicate device FlightPlan for Embolization [K193261].

In addition, the proposed device FlightPlan for Embolization includes an AI Segmentation option. The AI Segmentation option enabling both automatic segmentation of vasculature and automatic definition of the root point is based on two new algorithms: Deep-Learning based automatic vessels extraction algorithm and Deep-Learning based root definition algorithm.

For both vessels extraction algorithm and root definition algorithm, contrast injected CBCT scans acquired from GE HealthCare's interventional X-ray system [K181403] were used for designing and qualifying the algorithms. A test set of 207 contrast injected scans was reserved, segregated, and used to evaluate both algorithms.

Device Modification Overview:

The table below summarizes the substantive feature/technological differences and similarities between the predicate device and the proposed device:

Specification	**Predicate Device: FlightPlan for Embolization [K193261]**	**Proposed Device: FlightPlan for Embolization [K223490]**
Indication for Use	Identical	Identical
Patient Population	No limitations on the patient population.	AI Segmentation option is validated for adult population only.
Semi-automatic segmentation of vasculature	Identical	Identical
Automatic segmentation of vasculature	No, segmentation of vasculature can only be done semi-automatically	Yes, automatic segmentation of vasculature powered by Deep-Learning based algorithm
Automatic definition of the root point	No, definition of the root point can only be done manually	Yes, automatic definition of the root point powered by Deep-Learning based on algorithm
Selective display (Live Tracking)	Identical	Identical
Segment part of the vasculature	Yes	Yes
Mark points of interest (POI)	Yes	Yes
Save and Export	Yes	Yes
General features	Identical	Identical

Determination of Substantial Equivalence:

Summary of Non-Clinical, Design Control Testing

The proposed device, FlightPlan for Embolization, has successfully completed the required design control testing per GE HealthCare Quality Management System. No additional hazards were identified, and no unexpected test results were observed. The proposed device complies with NEMA PS 3.1 - 3.20 Digital Imaging and Communications in Medicine (DICOM) Set (Radiology) standard. It was designed and will be manufactured under the Quality System Regulations of 21CFR 820 and ISO 13485.

The following quality assurance measures were applied to the development of the device:

- Requirements Definition
- Risk Analysis
- Technical Design Reviews
- Formal Design Reviews
- Software Development Lifecycle
- Performance testing (Verification, Validation)
- System Testing (Verification, Validation)

The proposed FlightPlan for Embolization has been successfully verified on the AW VolumeShare workstation [K110834] and AW Server [K081985] platforms. All of the testing and results did not raise new or different questions of safety and effectiveness other than those already associated with predicate device.

The substantial equivalence determination is also based on the software documentation for a MODERATE level of concern device.

Additional Non-Clinical Testing

Engineering bench testing of the two new algorithms for the AI Segmentation option demonstrated the new algorithms' capabilities to automatically segment vasculature and to automatically define root point using CBCT scans.

The segregated test set contained a mix of 207 contrast injected CBCT scans (each from a unique patient) acquired during the planning of embolization procedures from GE HealthCare's interventional X-ray system [K181403]. The scans were selected to be representative of the intended population in terms of anatomy (with a majority of cases from head, liver, and prostate), vessel contrast and type of CBCT acquisition.

For vessel extraction, the ground truth was produced by the consensus of 3 board certified radiologists. For root definition, the ground truth was performed by a GEHC advanced application specialist.

The test set was used to evaluate the performance of the automatic vessels extraction algorithm compared to the best vessels segmentation result obtained with the semi-automatic tool in the predicate device; the success rate is 93.7% with acceptance criterion 90%. The same test set was used to evaluate the performance of the root definition algorithm compared to the acceptable area manually defined by the annotator; the success rate is 95.2% with acceptance criterion 90%.

Subgroup analyses were performed in the following areas: anatomy, vessel contrast, type of CBCT acquisition, and reconstruction filters. Since the critical input data for the algorithms are high contrast images of vessels with an intra-arterial injection acquired only on GE HealthCare interventional C-arms with similar acquisition protocol in all sites, and since there is minimal variation in this vessel anatomy across race/gender, standard sub-groups such as imaging device manufacturer, site, race, gender, are not relevant. The test results of both algorithms, including the subgroup analyses, support the acceptable performance of the algorithms in the intended population and indications for use.

Summary of Clinical Testing

Representative clinical sample images of 3D X-ray angiography from clinical sites were assessed by interventional radiologists using a 5-point Likert scale. The clinical assessment demonstrated that the proposed device FlightPlan for Embolization with AI Segmentation option met its pre-defined acceptance criteria and helps physicians in their analysis of 3D X-ray angiography images and in the planning of embolization procedures, including the selection of embolization injection points. As well, this activity substantiated the performance of the two Deep-Learning based algorithms, for automatic segmentation of vessels and automatic root point definition.

Substantial Equivalence Conclusion

The changes to predicate device FlightPlan for Embolization cleared in 2020 do not create new Intended Use nor Indication for Use. The proposed device FlightPlan for Embolization has identical or equivalent technological characteristics as its predicate device.

GE HealthCare's quality system's design, verification, and risk management processes did not identify any new questions of safety or effectiveness, hazards, unexpected results, or adverse effects stemming from the changes to the predicate.

Based on development under GE HealthCare's quality system, successful design verification, software documentation for a "Moderate" level of concern, along with the engineering bench testing and the clinical evaluation demonstrate that the proposed FlightPlan for Embolization is substantially equivalent to, and hence as safe and as effective for its Intended Use as the legally marketed predicate device.