GE Medical Systems SCS
c/o Ning Wen
Regulatory Affairs Leader
283, rue de la Miniere
BUC, 78530
FRANCE

January 24, 2020

Re: K193261
Trade/Device Name: FlightPlan for Embolization
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: November 25, 2019
Received: November 26, 2019

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); 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193261

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.

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 22, 2019
Submitter:	GE Medical Systems SCS Establishment Registration Number - 9611343 283, rue de la Minière 78530 Buc, France
Primary Contact Person:	Ning WEN Regulatory Affairs Leader GE Healthcare, (GE Medical Systems SCS) Tel: +33 1 3070 5668 Email: ning.wen@ge.com
Secondary Contact Person:	Philip Malca Director - Regulatory Affairs, Interventional & Surgery GE Healthcare, (GE Medical Systems SCS) Tel: +33 6 4637 3852 Email: philip.malca@ge.com
Device Trade Name:	**FlightPlan for Embolization**
Common/Usual Name:	Picture Archiving and Communications System
Classification Names:	21CFR 892.2050, Class II
Product Code:	LLZ
Predicate Device(s):	K121200, FlightPlan for Liver
Device Description:	FlightPlan for Embolization is a post processing software application which operates on the Advantage Workstation (AW) [K110834] platform and AW Server [K081985] platform. It is an extension to the Volume Viewer application [K041521] modified from FlightPlan for Liver (K121200) and is designed for processing 3D X-ray angiography images to help visualize vasculature.

	The primary features of the software are: • semi-automatic segmentation of vascular tree from a starting point determined by the user; • 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 vasculature; • ability to mark points of interest (POI) to store cursor position; • save results and export to other applications such as 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.
Indication for 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 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.
Technology:	The proposed device (FlightPlan for Embolization) employs the same fundamental scientific technology as its predicate device (FlightPlan for Liver). The proposed device (FlightPlan for Embolization) is a selective display tool helping user's visualization of vascular structures.

<table>
<tr>
<td>Comparison:</td>
<td>The table below summarizes the feature/technological comparison between the predicate device and the proposed device:
<table>
<tr><th>Specification</th><th>Predicate Device:

FlightPlan for Liver [K121200]</th><th>Proposed Device:

FlightPlan for Embolization</th></tr>
<tr><td>Segmentation of the vasculature</td><td>Yes, Semi-automatic</td><td>Yes, Semi-automatic</td></tr>
<tr><td>Segmentation and selective display of part of the vasculature</td><td>Yes, using target defined by user</td><td>Yes, using tool for live tracking of vessels</td></tr>
<tr><td>Identification of Points of interest</td><td>Yes</td><td>Yes</td></tr>
<tr><td>Save and Export</td><td>Yes</td><td>Yes</td></tr>
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<td>Determination of Substantial Equivalence:</td>
<td><u>Summary of Non-Clinical Tests:</u>

Engineering has validated FlightPlan for Embolization algorithms' capability to automatically segment and selectively display vascular structures from a single user defined point using a database of XACT exams. This database of exams is considered representative of the clinical scenarios where FlightPlan for Embolization is intended to be used, with consideration of acquisition parameters, image quality and anatomy. The result of the algorithms' validation established satisfactory quality for FlightPlan for Embolization usage.

The FlightPlan for Embolization complies with NEMA PS 3.1 - 3.20 (2016) Digital Imaging and Communications in Medicine (DICOM) Set (Radiology) standard.

FlightPlan for Embolization has successfully completed the required design control testing per GE's quality system. FlightPlan for Embolization 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:
▪ Risk Analysis</td>
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	▪ Requirements Reviews ▪ Design Reviews ▪ Performance testing (Verification, Validation) ▪ Safety testing (Verification) The substantial equivalence determination is also based on the software documentation for a MODERATE level of concern device. <u>Summary of Clinical Tests:</u> A sample of 3D X-ray angiography images representative of clinical practice was assessed by four board certified interventional radiologists using a 5-point Likert scale. These datasets represent the most common anatomic regions where embolization procedures are performed. The assessment demonstrated that the proposed device (FlightPlan for Embolization) helps physicians in the analysis of 3D X-ray angiography images and in the planning of embolization procedures, including the selection of embolization injection points.
Conclusion:	GE Healthcare considers the FlightPlan for Embolization to be as safe, as effective, and performance is substantially equivalent to the predicate device.