October 22, 2021

GE Medical Systems SCS
% Ning Wen
Regulatory Affairs Leader
283, rue de la Miniere
Buc, 78530
FRANCE

Re: K210807
Trade/Device Name: FlightPlan for Liver
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: September 29, 2021
Received: September 30, 2021

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210807

Device Name

FlightPlan for Liver

Indications for Use *(Describe)*

FlightPlan for Liver is a post processing software package that helps the analysis of 3D X-ray angiography images of the liver. Its output is intended as an adjunct means to help visualize vasculature and identify arteries leading to the vicinity of hypervascular lesions in the liver. This adjunct information may be used by physicians to aid them in their evaluation of hepatic arterial anatomy during the planning phase of embolization 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 of Safety and Effectiveness

K210807

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

Date:	October 20, 2021
Submitter:	GE Medical Systems SCS Establishment Registration Number - 9611343 283, rue de la Minière 78530 Buc, France
Primary Contact:	Ning WEN Regulatory Affairs Leader GE Healthcare, (GE Medical Systems SCS) Tel: +33 6 4637 3852 Email: ning.wen@ge.com
Secondary Contact	John Jaeckle Chief Regulatory Affairs Strategist Tel: +1 262 424 9547 Email: john.jaeckle@ge.com
Device Trade Name: Common/Usual Name: Regulation Number: Product Code: Regulatory Class:	**FlightPlan for Liver** FlightPlan for Liver, with Parenchyma Analysis option 21CFR 892.2050, Medical image management and processing system LLZ Class II
Predicate Device: Device Name: Manufacturer: 510(k) number: Regulation Number: Product Code: Regulatory Class:	 FlightPlan for Liver GE Medical Systems SCS K121200 21CFR 892.2050, Medical image management and processing system LLZ Class II
Reference Device: Device Name: Manufacturer: 510(k) number: Regulation Number: Product Code: Regulatory Class:	 FlightPlan for Embolization GE Medical Systems SCS K193261 21CFR 892.2050, Medical image management and processing system LLZ Class II

Device Description and Marketed Devices:

FlightPlan for Liver with the Parenchyma Analysis option is a post-processing, software-only application using 3D X-ray angiography images (CBCT) as input. It helps physicians visualize and analyze vasculature to aid in the planning of endovascular embolization procedures in the liver. It was developed from modifications to the predicate device, GE's FlightPlan for Liver [K121200], including the addition of 2 new algorithms supporting the Parenchyma Analysis option. The Parenchyma Analysis option is what triggered this 510k.

The subject device also includes a feature, Live Tracking, that was cleared in the reference device, GE's FlightPlan for Embolization. The software operates on GE's Advantage Workstation [K110834] platform and AW Server [K081985] platform and is an extension to the GE's Volume Viewer application [K041521].

The primary features of the software are:

- Multi-modality 3D review to load and compare CBCT, CT, MR, PET, NM dataset side by side with a CBCT dataset.
- Semi-automatic segmentation of the liver arterial tree from an operator-defined starting point in the CBCT images.
- Definition by operator of target(s).
- Semi-automatic segmentation (displayed using color highlights) of vessels from the operator-defined starting point to the vicinity of each target. The vessels are semi-automatically highlighted and are called "vicinity vessels".
- Ability to manually add and remove vessels in the vicinity of the targets.
- Selective display (Live Tracking) of both proximal vessel and distal vessels interactively from a reference point determined by the user's cursor on the vessel, used also in the reference device FlightPlan for Embolization.
- Ability to mark points of interest (POI) to store a cursor position.
- The Parenchyma Analysis option which includes the two new algorithms which triggered this 510k:
  - The deep learning-based Liver Segmentation algorithm that performs an automated segmentation of the entire liver on injected CBCT acquisitions. The outputted liver segmentation is an intermediate result that is used as a boundary for the second algorithm, Virtual Parenchyma Visualization (VPV).
  - The non-deep learning Virtual Parenchyma Visualization algorithm that selectively displays, for visualization purposes, the *estimated* distal liver region adjacent to the distal parts of the computed skeleton of the vessel segmentation (Virtual Parenchyma) interactively from a user-determined reference point(s).
- Saving of results and export optionally to GE's Vision application [K092639] for 3D road-mapping.

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

(1) Planning, using 2D 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 points using 2D DSA and Selective CBCT.
(4) Treatment, phase which consists into injection of drug to the confirmed treatment points.
(5) Control, to assess the embolization procedure end-point.

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

Intended Use:

FlightPlan for Liver is a post processing software package that helps the analysis of 3D X-ray angiography images of the liver. Its output is intended to be used by physicians as an adjunct means to help visualize vasculature and identify arteries leading to the vicinity of hypervascular regions of interest in the liver.

Indication for Use:

FlightPlan for Liver is a post processing software package that helps the analysis of 3D X-ray angiography images of the liver. Its output is intended as an adjunct means to help visualize vasculature and identify arteries leading to the vicinity of hypervascular lesions in the liver. This adjunct information may be used by physicians to aid them in their evaluation of hepatic arterial anatomy during the planning phase of embolization procedures.

Technology:

The proposed device, FlightPlan for Liver, employs the same fundamental scientific technology as its predicate device (FlightPlan for Liver) and its reference device (FlightPlan for Embolization).

In addition, the proposed device FlightPlan for Liver includes selective display tools helping user's visualization of vascular structures as well as estimated distal liver regions adjacent to distal vessels. The selective display of vessels (Live Tracking) and the selective display of estimated distal liver regions (Virtual Parenchyma) are interactive with user's cursor, based on the computed skeleton of the vessel tree segmentation for Live Tracking and on two new algorithms: deep learning-based Liver Segmentation algorithm; and non-deep learning Virtual Parenchyma Visualization algorithm for Virtual Parenchyma.

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 Liver [K121200]**	**Proposed Device: FlightPlan for Liver**
Multi-modality 3D review & comparison of CBCT, CT, MR, PET, NM datasets	Identical	Identical
Semi-automatic segmentation of the liver arterial tree	Yes	Yes
Definition by operator of target(s)	Yes	Yes

Specification	Predicate Device: FlightPlan for Liver [K121200]	Proposed Device: FlightPlan for Liver
Semi-automatic segmentation of "vicinity vessels"	Yes	Yes
Ability to manually add and remove "vicinity vessels"	Identical	Identical
Segmentation and selective display of parts of the vasculature	Yes, using target defined by user.	Yes, using tool for Live Tracking of vessels.
Ability to mark POIs	Yes	Yes
Deep learning-based full Liver Segmentation	No, full liver segmentation can only be done manually.	Yes, DL based automated segmentation of the full liver.
Selective display of the estimated distal liver region (Virtual Parenchyma)	No	Yes, the non-deep learning Virtual Parenchyma Visualization algorithm selectively displays, for visualization purposes, the estimated distal liver region adjacent to the distal parts of the computed skeleton of the vessel segmentation (Virtual Parenchyma).
Save and export	Identical	Identical
Platform	Advantage Workstation	Advantage Workstation, AW Server

Determination of Substantial Equivalence:

Summary of Non-Clinical, Design Control Testing

FlightPlan for Liver has successfully completed the design control testing per GE's quality system. No additional hazards were identified, and no unexpected test results were observed. The proposed device complies with NEMA PS 3.1 - 3.20 (2016) Digital Imaging and Communications in Medicine (DICOM) Set (Radiology) standard.

The proposed device, FlightPlan for Liver, has successfully completed the required design control testing per GE Healthcare Quality Management System. 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 Liver has been successfully verified on the AW VolumeShare workstation and AW Server platforms. All the testing and results did not raise new or different questions of safety and effectiveness other than those already associated with predicate device.

Software documentation for a MODERATE level of concern.

Additional Non-Clinical Testing

Engineering bench testing of the two new algorithms for the Parenchyma Analysis option demonstrated the new algorithms' capabilities to selectively display vascular structures and estimated distal liver region to support substantial equivalence and demonstrate performance.

A database of contrast injected CBCT liver acquisitions from clinical sites in the USA and France was used for the training and testing of the deep learning Liver Segmentation algorithm.

The non-DL Virtual Parenchyma Visualization algorithm's performance was evaluated using a test set of proximal CBCT acquisitions from the USA and France. This test set was used to evaluate the performance of the VPV algorithm compared to selective contrast injected CBCT exams from same patients used as the ground truth.

The variety of exams in the evaluations is representative of the clinical scenarios where FlightPlan for Liver with the Parenchyma Analysis option is intended to be used. The test results of both of the algorithms met their predefined acceptance criteria.

Summary of Clinical Testing

A sample of 3D X-ray angiography image pairs, from France and the USA, of non-selective CBCT and selective CBCT images representative of clinical practice in liver embolization were assessed by interventional radiologists using a 5-point Likert scale. The clinical assessment demonstrated that the proposed device FlightPlan for Liver with the Parenchyma Analysis option met its predefined acceptance criteria and helps physicians visualize and analyze 3D X-ray angiography images, can be used to estimate distal liver regions from a reference point, and aids in the planning of embolization procedures in the liver, including the selection of embolization injection points.

Substantial Equivalence Conclusion

The changes to FlightPlan for Liver cleared in 2012 do not create a new Intended Use. FlightPlan for Liver with the Parenchyma Analysis option has identical or equivalent technological characteristics as its predicate device and reference device.

GE'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 Liver with the Parenchyma Analysis option is substantially equivalent to, and hence as safe and as effective for its Intended Use as the legally marketed predicate device.