May 2, 2022

GE Medical Systems SCS
% Peter Uhlir
Regulatory Affairs Leader
283, rue de la Minière
Buc, 78530
FRANCE

Re: K211180
Trade/Device Name: Liver Suite
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK, LLZ
Dated: April 25, 2022
Received: April 26, 2022

Dear Peter Uhlir:

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,

Laurel Burk
Assistant Director
Diagnostic X-ray Systems Team
DHT 8B: 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)*

K211180

Device Name

Liver Suite

Indications for Use *(Describe)*

Liver Suite is an aiding tool for the clinician to review multi-phase liver CT images following LI-RADS® guidelines. Liver Suite is designed to help analyzing liver lesions in patients with known or suspected hepatocellular carcinoma (HCC). It provides optimized series display and a guided workflow to assess relevant clinical features for user-defined observations, to enable computation of a LI-RADS score. It is intended for use by healthcare professionals.
The clinician remains ultimately responsible for the final assessment and diagnosis based on state-of-the-art practices, clinical judgment and interpretation of liver images or quantitative data.

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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K211180

510(k) Summary

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

Date:	May 2, 2022
Submitter:	GE Medical Systems SCS
	Establishment Registration Number - 9611343
	283 rue de la Minière
	78530 Buc, France
Primary Contact:	Peter Uhlir
	Regulatory Affairs Leader
	GE Healthcare, (GE Medical Systems SCS)
	Phone: +36 70 436 9317
	Email: peter.uhlir@ge.com
Secondary Contact:	Camille Vidal
	Director, Regulatory Strategy
	Phone: (240) 280-5356
	Email: camille.vidal@ge.com

Proposed Device:	
Device Name:	Liver Suite
Common/Usual Name:	Liver Suite
Regulation number/ Product Code:	21 CFR 892.1750 Computed tomography x-ray system / JAK
	21 CFR 892.2050 Medical image management and processing system / LLZ
Classification:	Class II

Predicate Device:	
Device Name:	Hepatic VCAR
510(k) number:	K193281 cleared on March 20, 2020
Regulation number/ Product Code:	21 CFR 892.1750 Computed tomography x-ray system / JAK
	21 CFR 892.2050 Picture archiving and communication system / LLZ
Classification:	Class II
Manufacturer:	GE Medical Systems SCS

Reference Device:	
Device Name:	PROView
510(k) number:	K193306 cleared on November 17, 2020
Regulation number/ Product Code:	21 CFR 892.2050 Picture archiving and communication system / LLZ
Classification:	Class II
Manufacturer:	GE Medical Systems SCS

Device Description: Liver Suite is a medical software that offers a guided workflow for the review and assessment of multi-phase CT liver exams per LI-RADS® v2018 guidelines. It is designed to help analyze liver lesions in patients with known or suspected hepatocellular carcinoma (HCC) by providing optimized image display and assessment of intensity metrics related to the 3 major imaging features for LI-RADS scoring.

Liver Suite takes phased contrast CT series as input. It only processes one exam at a time (no longitudinal analysis).

Liver Suite guided workflow includes:

- Automatic phase identification of the four hepatic imaging phases: unenhanced, arterial, portal venous and delayed
- Semi-automatic lesion contouring based on an initial deposition from the user, user selects applicable appropriate score (LRNC, LR-TIV, LR-1, LR-2 or LR-M) based on image review
- A user interface to guide the user in the application of LI-RADS scoring guidelines v2018
- User sets the features - non-rim APHE (Yes/No), Enhancing Capsule (Yes/No), Non-peripheral washout (Yes/No), Threshold growth (Yes/No/Not Applicable), Ancillary Features
- Automated computation of intensity metrics to help characterize Arterial Phase Hyper Enhancement (APHE), Washout and Capsule
- Automated calculation of LI-RADS score (per LI-RADS v2018 guidelines) from user assessment of major and ancillary features
- Display of all measurements in a table for review and export

Identification of hepatic phases is based on a model-based algorithm or can be set manually by the user. Semi-automatic contouring of the lesion is based on the Auto Contour feature and user input. The Auto Contour feature is already part of Volume Viewer (K041521).

User sets LI-RADS major and ancillary features and compute associated LI-RADS score. To assist with the assessment of Arterial Phase Hyper Enhancement (APHE), Washout and Capsule, intensity metrics based on enhancement characteristics around the lesion are automatically computed.

LI-RADS score is computed based on LI-RADS features using LI-RADS diagnostic table. User can edit the major features, add ancillary features or manually choose a different score.

Intended Use: Liver Suite is a medical diagnostic software that provides the clinician with tools to efficiently process, analyze, review and communicate to peers findings from liver CT image data. The combination of acquired images, reconstructed images, annotations and measurements performed by the clinician are intended to provide the referring physician with clinically relevant information that may aid in diagnosis and patient management.

Indication for Use: Liver Suite is an aiding tool for the clinician to review multi-phase liver CT images following LI-RADS® guidelines. Liver Suite is designed to help analyzing liver lesions in patients with known or suspected hepatocellular carcinoma (HCC). It provides optimized series display and a guided workflow to assess relevant clinical features for user-defined observations, to enable computation of a LI-RADS score. It is intended for use by healthcare professionals. The clinician remains ultimately responsible for the final assessment and diagnosis based on state-of-the-art practices, clinical judgment and interpretation of liver images or quantitative data.

Technology: Liver Suite software provides a workflow to assess hepatocellular carcinoma following LI-RADS guidelines using multi-phase liver CT images which are routine acquisitions, systematically done by the clinician for liver cancer assessment in case of hepatocellular carcinoma, as it is part of LI-RADS guidelines.

Liver Suite is a post processing application option that is intended for the analysis of CT liver images. It is embedded in Volume Viewer (K041521). Volume Viewer is a platform of 3D applications that provides at the same time an autonomous set of layouts, protocols and tools for the user and common framework to build other specialty 3D applications on top of Volume Viewer, such as proposed application Liver Suite. Liver Suite and Volume Viewer run on AW VolumeShare Workstation (K110834) and AW Server (K081985) platforms, Cloud or PACS stations

Comparison: The table below summarizes the feature/technological comparison between the predicate device and the proposed device:

Specification	**Predicate Device: Hepatic VCAR (K193281)**	**Proposed Device: Liver Suite**
Targeted clinical condition, anatomy and imaging modality	Clinical condition: patient with suspected or known liver lesions. Anatomy: Liver; Imaging modality: CT	Clinical condition: patient with suspected or known HCCs, which are a type of liver lesions. Anatomy: Liver; Imaging modality: CT
Lesion characterization	Automatic characterization of the lesion volume based on maximum 2D diameter given manually by the user. User can review and edit the contour. Once accepted, the following statistics are available: - lesion volume - lesion 2D max and short axis	Automatic characterization of the lesion volume based on maximum 2D diameter given manually by the user. User can review and edit the contour. Once accepted, the following statistics are available: - lesion volume

	- lesion HU values (min, max, average, standard deviation)	- lesion 2D max and short axis - lesion HU values (min, max, average, standard deviation) - 3 intensity metrics: Arterial Phase Hyper Enhancement (APHE), Washout and Capsule based on analysis of intensity enhancement differences between the lesion and adjacent parenchyma. User sets LI-RADS major and ancillary features in workflow panel to enable computation of the associated LI-RADS score.
Automatic phase identification	Automatic detection of portal phase based on image information. User can modify series display if needed.	Automatic detection of uncontrasted, arterial, portal and delayed phase based on a statistical model using image and acquisition information. User can modify series display if needed.
Summary Report Content	Organ type bookmarks: • Liver • Portal Vein • Hepatic Artery • Segment Lesion type bookmarks: • Lesion	For each lesion Observation Analysis finding: • Observation size • Observation major features • Observation ancillary features • Observation LI-RADS score

Specification	**Reference Device: PROView (K193306)**	**Proposed Device: Liver Suite**
Computation of PI/LI-RADS score	Based on user input on location and assessment Following PI-RADS™ v2.1 guidelines	Based on user input on major and ancillary features Following LI-RADS® v2018 guidelines

Determination of Substantial Equivalence:

The proposed device, Liver Suite, has successfully completed the required design control testing per GE Healthcare Quality Management System. Liver Suite was designed and will be manufactured under the Quality System Regulations of 21CFR 820 and ISO

13485:2016. The proposed device complies with NEMA PS 3.1 - 3.20 (2016) Digital Imaging and Communications in Medicine (DICOM) Set (Radiology) standard.

The following quality assurance measures have been applied to the development of the system:

- Risk Analysis
- Required Reviews
- Design Reviews
- Software Development Lifecycle
- Performance testing (Verification)
- Safety testing (Verification)
- Algorithm Qualification (Validation)

Liver Suite has been verified on AW workstation (K110834) and AW Server (K081985) platforms. The substantial equivalence was also based on software documentation for a "Moderate" level of concern device.

Engineering bench testing for the Liver Suite Phase Identification algorithm demonstrated the capabilities to identify automatically the two, three or four phases acquired on multi-phases CT images for LI-RADS scoring.

APHE, Washout and Capsule intensity metric calculation was verified through testing on synthetic images and validated by comparing intensity metric distribution on a set of expert-annotated lesions.

Conclusion: GE Healthcare considers the Liver Suite software application to be as safe, as effective, and performance is substantially equivalent to the predicate device.