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

November 22, 2022

Re: K223152
Trade/Device Name: Vision 2, EVARVision, TrackVision 2, HeartVision 2
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ, OWB
Dated: October 4, 2022
Received: October 6, 2022

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,

Jessica Lamb

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)*

K223152

Device Name
Vision 2, EVARVision, TrackVision 2, HeartVision 2

Indications for Use *(Describe)*

Vision 2, TrackVision 2, EVARVision and HeartVision 2 software applications are intended to enable users to load 3D datasets and overlay and register in real time these 3D datasets with radioscopic or radiographic images of the same anatomy in order to support catheter/device guidance during interventional procedures.

Structures of interest and estimated dimensions can be overlaid on the radioscopic or radiographic images. Image processing can be applied to enhance the display of such images. This information is intended to assist the physician during interventional procedures.

The Stereo 3D option enables physicians to visualize and localize needles, points, and segments on a 3D model/space using a stereotactic reconstruction of radioscopic or radiographic images at a significantly lower dose than use of a full cone beam CT acquisition. This information is intended to assist the physician during interventional 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K223152

510(k) Summary of Safety and Effectiveness

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

Date:	October 4, 2022
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: +1 608 515 3077 Email: ning.wen@ge.com
Secondary Contact	Camille VIDAL Senior Regulatory Affairs Director Tel: +1 410 948 3137 Email: camille.vidal@ge.com
Device Trade Name: Common/Usual Name: Primary Regulation Number: Primary Product Code: Secondary Product Code: Regulatory Class:	**Vision 2**, **EVARVision**, **TrackVision 2**, **HeartVision 2** **Vision Applications** 21CFR 892.2050, Medical image management and processing system LLZ OWB Class II
Primary Predicate Device: Device Name: Manufacturer: 510(k) number: Regulation Number: Product Code: Regulatory Class:	 Innova Vision Applications GE Medical Systems SCS K092639 21CFR 892.2050, Medical image management and processing system LLZ Class II
Secondary Predicate Device: Device Name: Manufacturer: 510(k) number: Regulation Number: Product Code: Regulatory Class:	 Stereo 3D option for Vision Applications GE Medical Systems SCS K152352 21CFR 892.2050, Medical image management and processing system LLZ, OWB Class II

Reference Device:	
Device Name:	Innova IGS 5, Innova IGS 6, Discovery IGS 7, Discovery IGS 7 OR
Manufacturer:	GE Medical Systems SCS
510(k) number:	K181403
Regulation Number:	21CFR 892.1650, Image-intensified fluoroscopic x-ray system
Product Code:	OWB, JAA, IZI, OXO
Regulatory Class:	Class II

Device Description and Marketed Devices:

Vision Applications are a group of software applications called **Vision 2**, **EVARVision**, **TrackVision 2** and **HeartVision 2** that share the same core functionalities to target different clinical procedures.

Vision Applications load 3D datasets previously acquired from an acquisition modality (CT, MR or CBCT) and prepared with Volume Viewer application [K041521]. They overlay and register in real-time these 3D datasets with the 2D X-ray live images acquired from the GE Interventional X-ray system [K181403] (called IGS X-ray system in the rest of the document) to help support localization and guidance of catheters / devices during interventional procedures, in conjunction with primary images, native live 2D X-ray images.

Vision Applications help physicians to perform interventional procedures by providing enhanced image quality and additional 3D information instead of 2D X-ray live images alone.

Vision Applications operate on GE's Advantage Workstation (AW) [K110834] platform and communicates with the IGS X-ray system [K181403] for receiving the live X-ray images.

The subject device, Vision Applications were developed from modifications to the primary predicate device Innova Vision Applications [K092639], including the addition of new optional feature "**Digital Pen**". The Digital Pen option is what triggered this 510k and was modified from the reference device, GE's IGS X-ray systems [K181403] under the name Stenosis Analysis. The Vision Applications include also Stereo 3D option feature [K152352, secondary predicate].

The primary features/functionalities of the Vision Applications are:

- Digital Pen.
- Overlay of 2D/3D images.
- Reception and display of live 2D images and related information.
- Loading of 3D datasets.
- Review mode.
- Film/Sequence/photo store.
- Display controls for Visualization of images: including Zoom/Roam, Rendering, Planning data display, Annotation display, Virtual Collimation, ECG Display, Calcification Visualization Enhancement, display adjustment tools.
- Automatic Registration: including A priori registration and Registration based on Augmented Calibration.
- Manual Registration.

- Bi-view registration.
- User Interface: control from AW and from Tableside.
- 2D Modes.
- Send Angles: including EVAR Angles, Progress View/Bull's eye.
- Stereo 3D.

Intended Use:

Vision 2, EVARVision, TrackVision 2 and HeartVision 2 software applications are intended to enable users to load 3D datasets and overlay and register in real time these 3D datasets with radioscopic or radiographic images of the same anatomy in order to support catheter/device guidance during interventional procedures.

Indication for Use:

Vision 2, TrackVision 2, EVARVision and HeartVision 2 software applications are intended to enable users to load 3D datasets and overlay and register in real time these 3D datasets with radioscopic or radiographic images of the same anatomy in order to support catheter/device guidance during interventional procedures.

Structures of interest and estimated dimensions can be overlaid on the radioscopic or radiographic images. Image processing can be applied to enhance the display of such images. This information is intended to assist the physician during interventional procedures.

The Stereo 3D option enables physicians to visualize and localize needles, points, and segments on a 3D model/space using a stereotactic reconstruction of radioscopic or radiographic images at a significantly lower dose than use of a full cone beam CT acquisition. This information is intended to assist the physician during interventional procedures.

Technology:

The proposed device Vision Applications employ the same fundamental scientific technology as its predicate devices Innova Vision Applications and Stereo 3D.

In addition, the proposed device Vision Applications include Digital Pen option. The Digital Pen option provides the ability to draw objects on the Viewer and to perform dimension estimations on 2D X-ray images, based on the same technology employed in the cleared Stenosis Analysis option from the reference device, GE's IGS X-ray systems [K181403].

Device Modification Overview

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

Specification	**Primary Predicate Device: Innova Vision Applications [K092639]**	**Proposed Device: Vision Applications**
Digital Pen	No, user can draw objects and perform dimension estimation	Yes, user can draw objects and perform dimension estimation

	by using separate Stenosis Analysis feature cleared in reference device [K181403]	by using directly Digital Pen optional feature embedded in Vision Applications
Overlay of 2D/3D images	Identical	Identical
Reception and display of live 2D images and related information	Yes	Yes
Loading of 3D datasets	Identical	Identical
Review mode	Yes	Yes
Film / Sequence / photo store	Identical	Identical
Zoom / Roam	Identical	Identical
Rendering	Yes	Yes
Planning data display	Yes	Yes
Virtual Collimation	No, Virtual Collimation exists in IGS X-ray system [K181403]	Yes, Virtual Collimation information is duplicated in Vision Applications
ECG Display	Identical	Identical
Calcification Visualization Enhancement	No, moving /contrasted structures are visible on live X-ray, but without visualization enhancement.	Yes, enhanced visualization of moving contrasted structures is optionally available.
Display adjustment tools	Yes	Yes
A priori registration	Identical	Identical
Registration based on Augmented Calibration	Yes	Yes
Manual Registration	Yes	Yes
Bi-view registration	No, only manual single-view registration	Yes, Bi-view registration
User Interface	Yes, from Advantage Workstation and Tableside	Yes, from Advantage Workstation and Tableside
2D Modes	Yes	Yes
Send Angles	Yes	Yes
Progress View / Bull's eye	Identical	Identical
Specification	**Secondary Predicate Device: Stereo 3D option for Vision Applications [K152352]**	**Proposed Device: Vision Applications**
Stereo 3D	Identical	Identical

Determination of Substantial Equivalence:

Summary of Non-Clinical, Design Control Testing

The proposed device, Vision Applications, 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 Digital Imaging and Communications in Medicine (DICOM) Set (Radiology) standard.

The proposed device, Vision Applications, has successfully completed the required design control testing per GE Healthcare Quality Management System. It was designed and 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 device, Vision Applications, has been successfully verified on the AW VolumeShare workstation [K110834] together with the IGS X-ray systems [K181403]. All of the testing and results did not raise new or different questions of safety and effectiveness other than those already associated with predicate devices.

Software documentation for a MODERATE level of concern.

Additional Non-Clinical Testing

Engineering bench testing was used to support substantial equivalence and demonstrate performance.

Engineering has validated the dimension estimation accuracy of Digital Pen option using a phantom with series of known dimension and simulated use conditions.

The variety of test conditions in the evaluations is representative of the clinical scenarios where Digital Pen option of Vision Applications is intended to be used. The test results met the predefined acceptance criteria.

Summary of Clinical Testing

The subject of this premarket submission, Vision Applications, did not require clinical studies to support substantial equivalence.

Substantial Equivalence Conclusion

The changes to predicate device cleared in 2009 do not create a new Intended Use. Vision Applications with the Digital Pen option has identical or equivalent technological characteristics as its predicate devices 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 predicates.

Based on development under GE Healthcare's quality system, successful design verification, software documentation for a "Moderate" level of concern, along with engineering bench testing demonstrate that the proposed Vision Applications with the Digital Pen option is substantially equivalent to, and hence as safe and as effective for its Intended Use as the legally marketed predicate devices.