DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

GE Medical Systems, SCS
% Mr. John Jaeckle
Regulatory Affairs Leader
283 rue de la MINIERE
Buc 78530
FRANCE

January 20, 2016

Re: K152352
Trade/Device Name: Stereo 3D option for Vision Applications
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ, OWB
Dated: December 11, 2015
Received: December 14, 2015

Dear Mr. Jaeckle:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152352

Device Name
Stereo 3D option for Vision Applications

Indications for Use *(Describe)*
Vision 2, 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.

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)

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510(k) Summary

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

Date:	11-December-2015
Submitter:	GE Healthcare, (GE Medical Systems SCS) 283 rue de la MINIERE 78530 Buc, France
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Device Trade Name:	**Stereo 3D option for Vision Applications**
Common/Usual Name:	Stereo 3D option for Vision Applications
Classification Names: Product Code: Class:	Picture archiving and communications system Image-intensified fluoroscopic x-ray system LLZ - 21CFR 892.2050 OWB – 21CFR 892.1650 II

Primary Predicate Device(s):	K092639, Innova Vision Applications (from GE Healthcare) Product code: LLZ; Regulation number: 892.2050.
Second Predicate Device(s):	K052412, Innova 3D (from GE Healthcare) Product code: OWB, JAA; Regulation number : 892.1650.
Device Description:	Vision Applications (K092639) includes Vision 2, TrackVision 2 and HeartVision 2 applications. Vision Applications can load and dynamically fuse in real-time live 2D X-ray images from the X-ray system with 3D models from X-Ray (DICOM 3D XA), CT or MR system. Stereo 3D is a new option and the subject of this submission. The Stereo 3D option is designed to be used with the Vision 2 and TrackVision 2 applications which are part of Vision Applications. The Stereo 3D option enables the user to reconstruct 3D objects from radioscopic or radiographic images. The Stereo 3D option intends to provide an alternative to intra operative CBCT (cone beam CT) usually performed for the same purpose: to localize needles and markers within the 3D anatomy. The Stereo 3D option provides a method to reconstruct 3D contrasted objects (point and segments) from a pair of 2D X-ray images, e.g. acquisition of fluoroscopic images from different C-arm positions (2 different projections). The 3D object reconstruction is then fused in the 3D space with the 3D model used at the fusion of the x-ray image. Stereo 3D has a workflow that is significantly guided, to support clear and easy use of the reconstruction procedure. The workflow contains the following 4 high level steps: • Image acquisition and registration adjustment • Automatic or manual object identification • Quality assessment of 3D reconstruction • Display of the reconstructed point(s) and segment(s) on a cross section of the 3D model. The second step (object identification) can be done manually or automatically: <u>Manual point(s) or segment(s) identification:</u> After the acquisition and registration of the two x-ray images acquired at two different C-arm positions, the user has to manually select points on the two x-ray images which correspond to the object to reconstruct (e.g. endograph markers and needles). <u>Automatic Mode for needles (only with Trackvision 2):</u> The user first selects a planned trajectory with a needle inserted.

	After the acquisition of the two X-ray images, and the registration adjustment phase, the needle will automatically be detected and reconstructed.
Intended Use:	Vision 2, 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 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. 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:	Vision Applications are software applications that execute on the Advantage Workstation (AW) review workstation [K110834]. The live fluoroscopic images, as well as the necessary exam data, are transmitted from the Interventional fluoroscopic X-ray system to the AW through a dedicated link. The 3D datasets previously acquired (from XA only for TrackVision 2, and from XA, CT and MR for Vision 2 and HeartVision 2) are loaded from the AW database. The 3D-2D fusion and the user interface of the application are displayed on the AW main screen, which is distributed identically in both the Control and Exam Rooms, The most frequently used functions are available from the Central Touch Screen at table side in the exam room. This user interface is controlled by the application through the Interventional fluoroscopic X-ray system Ethernet network. The Vision Applications employ the same fundamental scientific technology as its primary predicate devices. The new Stereo 3D option is an embedded software component of the Vision 2 and/or TrackVision 2 components of Vision Applications. This option is designed to reconstruct 3D object(s). Stereo 3D contains the algorithms used to detect the 2D needles on the image and to reconstruct points, needles and segments in 3D from fluoroscopic images. Stereo 3D option is based on the 3D reconstruction technology of "Innova 3D" [K052412] that is second predicate device and also runs on AW platforms.

	The reconstructed 3D objects can be displayed by Vision Applications on the initial 3D model (fused with live 2D), and exported to Volume Viewer [K041521]. All causes of hazard relative to the introduction of Stereo 3D option have been identified and mitigated.
Determination of Substantial Equivalence:	The following testing was used to assess safety and effectiveness and, thus, to establish the substantial equivalence with the predicate devices. <u>Summary of Non-Clinical Tests:</u> The Stereo 3D option for Vision Applications comply with NEMA PS 3.1 - 3.20 (2011) Digital Imaging and Communications in Medicine (DICOM) Set and with voluntary standards IEC 62304 (2006) and IEC 62366 (2007). The following quality management measures were applied to the development of the software application: • Product verification ensures the software conforms to its requirements including hazard mitigations risk management requirements. The verification tests confirmed that design output meets design input requirements. The tests were executed at component, software subsystems, and system levels. Functional testing and performance testing are part of system level verification. Performance has been confirmed with bench testing • Simulated Use Testing ensured the system conforms to user needs and intended uses through simulated clinical workflows using step-by step procedures that would be performed for representative clinical applications. • Usability validation testing is conducted to confirm that the product can be used safely and effectively. The participants used for this testing were licensed and/or clinically trained healthcare providers or users. • Additional bench testing was performed to substantiate Stereo 3D's product claims. <u>Summary of Clinical Tests:</u> The Stereo 3D option for Vision Applications did not require clinical studies to assess safety and effectiveness and, thus, to establish the substantial equivalence. Stereo 3D is based on established GE technology which enabled use of our "typical" verification and validation testing methods. Additionally, engineering bench testing was able to be performed using existing phantoms, methods, and performance metrics. The above testing was able to fully test that our design input

	requirements were met and there were not any unexpected results.
Conclusion:	GE Healthcare considers the Stereo 3D Option for Vision Applications to be as safe and as effective and substantially equivalent to the predicate devices. This conclusion is based on: • Verification and Validation testing has demonstrated that the design inputs, user requirements, and risk mitigations have been met. • Bench testing has demonstrated the performance and substantiated the claims of Stereo 3D. • The results of design validation did not raise new issues of safety and effectiveness. • The successful completion of the above testing was sufficient to assess safety and effectiveness and, thus, to establish the substantial equivalence. • The Stereo 3D Option for Vision Applications does not raise new issues of safety and effectiveness. • The Stereo 3D Option for Vision Applications does not introduce new fundamental scientific technology.