DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 9, 2016

GE Hangwei Medical System Co., Ltd.
% Lv Rui
Regulatory Affairs Leader - Product MICT
No.1, Yong Chang Street,
Beijing Economic & Technical Development Area
Beijing, 100176
CHINA

Re: K153429
Trade/Device Name: SmartView 3D Option
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: January 26, 2016
Received: January 29, 2016

Dear Lv Rui:

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,

Michael D. O'Hara For

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)*
K153429

Device Name

SmartView 3D Option

Indications for Use *(Describe)*

The SmartView 3D option is used as part of a head or whole body CT interventional procedure when the physician desires to obtain a visualization, 3D orientation, and localization of the needle in patients of all ages. SmartView 3D can automatically detect various sized needles during CT interventional procedures. SmartView 3D reconstructs and displays the traditional 2D images, and immediately thereafter additionally displays Multiple Planar Reconstruction images from a reconstruction in an orthogonal reference frame aligned with the needle's orientation where the needle tip is at the origin. This additional information may aid in guidance and/or monitoring 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.

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510(k) Summary - SmartView 3D Option

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

Date:	January 26, 2016
Submitter:	GE Healthcare GE Healthcare (GE Medical Systems, LLC) 3000 N. Grandview Blvd W-1140 Waukesha, WI 53188
Primary Contact Person:	Lv Rui Regulatory Affairs Leader GE Healthcare (GE Hangwei Medical systems, Co, ltd) Phone Number: (86)-10-58068888-70163 Email: rui.lv@ge.com
Secondary Contact Person:	Huy Doan Regulatory Affairs Director, MI&CT GE Healthcare (GE Medical Systems, LLC) Tel: 262-312-7751 Fax: 262-364-2506 e-mail: huy.doan@med.ge.com
Device Trade Name:	SmartView 3D Option
Common/Usual Name:	Needle Detection Software Application for Computed Tomography X-ray System
Classification Names:	Computed Tomography X-ray System 21CFR892.1750
Regulatory Class	II
Product Code:	JAK
Predicated Device(s):	SmartView Option (K973168)
Manufacturer(s):	GE Hangwei Medical Systems Co., Ltd No. 1 North Yong Chang North Street Beijing Economy & Technology Development Zone Beijing, 100176, China
	GE Medical Systems, LLC (GE Healthcare) 3000 N. Grandview Blvd. Waukesha, WI 53188

Marketed Devices:

The GE SmartView 3D Option is of comparable type and substantially equivalent to the GE Healthcare's currently marketed SmartView Option (K973168).

Device Description:

The **GE SmartView 3D Option** is for use with a GE CT system. SmartView 3D is an enhanced software option to the current SmartView Option application (predicate device; K973168). The SmartView 3D Option is designed to be used during CT-guided interventional procedures with the ability to detect needles and produce, in a needle-based geometry, orthogonal 3D reformats. SmartView 3D displays the oblique Multiple Planar Reconstruction (MPR) images of the needle and provides 3D information of the needle orientation. The SmartView Option is intended to be used during CT interventional procedures with either a continuous fluoro acquisition mode or a step-and-shoot, single segment rotation acquisition mode, both of which create 2D axial images using the CT scanner's reference frame. When applied, the SmartView 3D option allows the user to acquire image data from a step-and-shoot, single segment rotation acquisition, which it then uses for the three MPR reconstructions (Needle-sagittal plane, Needle-axial plane, Needle-tip plane) that are able to be displayed simultaneously. SmartView 3D also displays 2D axial images reconstructed from the same acquisition. The 3D interventional viewports automatically update each time an acquisition is initiated with the foot pedal. SmartView 3D provides both the 2D axial reconstructions as well as the three MPR reconstructions which provide the physician with additional information for needle position visualization and localization for CT intervention procedures.

SmartView 3D Option was developed on Discovery CT590 RT/Optima CT580 system (K132410). Additionally, following minor changes to the CT system software were made to include functionality for installation and operation of the SmartView 3D Option:

Intended Use:

The SmartView 3D option is intended to reconstruct and process images acquired during CT interventional procedures and display the interventional device within a variety of 2D and 3D reformats, providing information to the physician for visualization, orientation, and location.

Indications for Use:

The SmartView 3D option is used as part of a head or whole body CT interventional procedure when the physician desires to obtain a visualization, 3D orientation, and localization of the needle in patients of all ages. SmartView 3D can automatically detect various sized needles during CT interventional procedures. SmartView 3D reconstructs and displays the traditional 2D images, and immediately thereafter additionally displays Multiple Planar Reconstruction images from a reconstruction in an orthogonal reference frame aligned with the needle's orientation where the needle tip is at the origin. This additional information may aid in guidance and/or monitoring during interventional procedures.

Technology:

The SmartView 3D Option uses the same fundamental image acquisition, reconstruction, processing, and display technology as: the predicate device and in general, CT scanners and post-processing software devices that are designed to identify imaged objects

The design of SmartView 3D adds a needle-specific detection algorithm to identify the needle, needle tip, and its 3D orientation. This information is used with conventional multi-planar reformatting (MPR) as currently used in the predicate device. The reformatted images are produced in a needle-based geometry with an orthogonal 3D reference frame. SmartView 3D provides both the initial 2D axial reconstructions as well as the three MPR reconstructions that provide the physician with additional information for needle position visualization and localization for CT interventional procedures.

Adverse Effects on Health:

Potential electrical, mechanical, and radiation hazards are identified in risk management including hazard analysis and controlled by:

- System verification and validation to ensure performance to specifications, Federal Regulations, and user requirements.
- Adherence to software development lifecycle procedures (SDLC)
- Instruction for Use provided for the safe an effective use by users.

The device is designed and manufactured under the Quality System Regulations of 21 CFR820.

Determination of Substantial Equivalence:

The GE SmartView 3D Option is of comparable type and substantially equivalent to the SmartView Option (K973168).

Verification bench testing showed that the GE SmartView 3D Option provides equivalent or better performance compared to SmartView Option Product development and testing has demonstrated that no adverse effects or new questions of safety or effectiveness have been introduced.

External clinical evaluation was not needed to establish safety and effectiveness. All changes were able to be fully evaluated on the bench, and the testing did not reveal any new questions of safety or effectiveness. GE believes the totality of all of the combined changes is considered substantially equivalent to the unmodified device.

In addition, the substantial equivalence determination was also based on software documentation for a "moderate" level of concern device.

Summary of Additional Testing

System and subsystem verification have been successfully executed under GE's quality system, which demonstrated the SmartView 3D option met design requirements. Engineering testing also included testing to substantiate the updated product claims and acceptance testing.

Clinical simulation bench testing was performed by an experienced interventional radiologist using the current production Discovery CT590 RT (K132410) CT system with the current production SmartView option (K973168) and the new SmartView 3D option. This testing included performance of needle biopsies on a variety of phantoms that are either used for training physicians on these types of procedures or, with the concurrence of the interventional radiologist, determined to be representative surrogates for evaluation of device performance. The test procedures were executed and the test results demonstrated that SmartView 3D is of clinical quality for its intended use and indications for use.

Conclusion

SmartView 3D is an enhanced software option to the current SmartView Option. It does not result in any new safety risks and performs as well as devices currently on the market. The SmartView 3D Option for use on GE CT systems complies with the same or updated standards, as well as 21CFR 1020.30 and 1020.33 regulations as the predicate device. All verification and validation testing was successfully perform as well as additional engineering bench testing and also clinical simulation testing performed by an experienced interventional radiologist. Given the preceding, GE Healthcare believes the GE SmartView 3D Option is safe and effective, and performs in a substantially equivalent manner to the predicate device SmartView Option.