GE Hangwei Medical Systems, Co., Ltd.
℅ Yonghui Han
Regulatory Affairs Leader
West Area of Building No.3, No.1 Yongchang North Road
Beijing, 100176
CHINA

January 16, 2020

Re: K192956
Trade/Device Name: Auto Positioning
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: October 18, 2019
Received: October 21, 2019

Dear Yonghui Han:

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

Section 4: Indications for Use Statement

Auto Positioning

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192956

Device Name
Auto Positioning

Indications for Use *(Describe)*

The Auto Positioning feature provides an alternate, streamlined and efficient workflow and performs quality and safety checks for the CT technologist in setting up CT examinations up to the initiation of the first scout scan.

Auto Positioning acquires 3D spatial information of the individual patient on the table and combines it with information from the selected protocol to automatically calculate and visually display the scout's start and end locations. Concurrently it checks for proper patient orientation, determines the table height for optimum patient centering, and checks for potential contact between the patient and the gantry. Upon acceptance by the technologist the patient is automatically moved to the correct scout start location.

Use of Auto Positioning is intended to provide consistent patient positioning for optimal image quality and automatic exposure control.

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.

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GE Healthcare

510(k) Premarket Notification Submission for Auto Positioning

510(k) Summary

Auto Positioning

510(k) Summary

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirement of 21 CFR Part 807.87(h).

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

Date:	October 19, 2019
Submitter:	GE Hangwei Medical System Co.,Ltd West Area of Building No.3, No.1 Yongchang North Road, Beijing Economic and Technological Development Area, BEIJING 100176 CHINA
Primary Contact Person:	**Mr. Yonghui Han** Regulatory Affairs Leader GE Healthcare Phone Number: (86)-10-57083350 e-mail: yonghui.han@ge.com
Secondary Contact Persons:	**John Jaeckle** Chief Regulatory Affairs Engineer and Strategist GE Healthcare Phone Number: 262-424-9547 e-mail: John.Jaeckle.com
	Helen Peng Sr Regulatory Affairs Director GE Healthcare Phone Number: 262-4248222 e-mail: hong.peng@ge.com
Product Identification	Auto Positioning
Device Trade Name:	Auto Positioning
Classification Names: Product Code:	Computed Tomography X-ray System, 21CFR892.1750 (Class II) 90-JAK
Manufacturer	GE Hangwei Medical System Co.,Ltd West Area of Building No.3, No.1 Yongchang North Road, Beijing Economic and Technological Development Area, BEIJING 100176 CHINA

Predict Device:

Device Name	GE's Optima CT660
510 (K) number	K131576
Regulation Number/ Classification	Computed Tomography X-ray System, 21 CFR 892.1750 / Class II
Product Code	90-JAK

Reference Device:

Device Name	Siemens SOMATOM CT family
510 (K) number	K173630
Regulation Number/ Classification	Computed Tomography X-ray System, 21 CFR 892.1750 / Class II
Product Code	90-JAK

Reference Device:

Device Name	GE's Revolution Maxima
510 (K) number	K192686
Regulation Number/ Classification	Computed Tomography X-ray System, 21 CFR 892.1750 / Class II
Product Code	90-JAK

Marketed Devices:

Auto Positioning provides both a streamlined workflow and enhanced quality and safety checks during the exam set up process up to the initiation of the first scout scan. Auto Positioning is built upon the existing workflow of the predicate device, GE Healthcare' s currently marketed Computed Tomography X-ray System Optima CT660 (K131576). It is of comparable type and substantially equivalent to Optima CT660 and the Siemens Reference device.

Auto Positioning is a patient positioning workflow enhancement tool and intended to work together with a GE CT System. It doesn't change the Intended Use or the Indications for Use of

the CT system it is used with. Auto Positioning's Intended Use aligns and correspond with the predicates device's Intended Use.

Device Description:

Auto Positioning is an optional feature developed for use with GE CT systems. The purpose of this feature is to provide both a streamlined workflow and enhanced quality and safety checks during the exam setup process up to the initiation of the first scout scan. Incorporation of this optional feature does not preclude the technologist from preforming the existing manual workflow on the CT system, if desired.

Auto Positioning uses a fixed, ceiling mounted, off the shelf, 2D/3D video camera that is capable of determining distances to points in its field of view. It displays standard RGB video images on the CT system's existing gantry-mounted touchscreens. Information from the standard output of the camera, precise spatial information of the individual CT system's gantry and table installation geometry, and information contained in the user-selected protocol is used to determine the anatomical landmark location and the start and end locations for the scout scan(s).

Information from the standard output of the camera, precise spatial information of the individual CT system's gantry and table installation geometry, and information contained in the user-selected protocol is used to determine the anatomical landmark location and the start and end locations for the scout scan(s).

Addition functionality of Auto Positioning includes performing safety checks for patient orientation and the potential for the patient to come into contact with the gantry while the patient is placed into the gantry and during scanning.

Intended Use:

Auto Positioning is intended for use with head, whole body, cardiac and vascular X-ray Computed Tomography applications.

Indications for Use:

The Auto Positioning feature provides an alternate, streamlined and efficient workflow and performs quality and safety checks for the CT technologist in setting up CT examinations up to the initiation of the first scout scan.

Auto Positioning acquires 3D spatial information of the individual patient on the table and combines it with information from the selected protocol to automatically calculate and visually display the scout's start and end locations. Concurrently it checks for proper patient orientation, determines the table height for optimum patient centering, and checks for potential contact between the patient and the gantry. Upon acceptance by the technologist the patient is automatically moved to the correct scout start location.

Use of Auto Positioning is intended to provide consistent patient positioning for optimal image quality and automatic exposure control.

Technology Comparison:

Auto Positioning's functionality in setting up CT examinations is an automated version of the existing steps in the predicate's (and other GE CTs') current manual workflow and does not change the underlying principles. In addition, Auto Positioning introduces enhanced quality and safety checks during the exam setup. At any time during the use of Auto Positioning the operator can switch back to manual positioning.

The Auto Positioning feature can only be used with a host CT system that has a compatible gantry touchscreen(s) and the Auto Positioning-specific software integrated onto the CT system's host computer. Auto Positioning's major components consists of the ceiling mounted camera, Auto Positioning software, calibration tools, and compatible gantry touchscreen(s).

Auto Positioning was first integrated on the GE Revolution Maxima (K192686) CT System. Auto Positioning shares very similar technology, hardware, and functions with the corresponding functionality of the reference device, Siemens SOMATOM CT family with FAST Integrated Workflow (K173630).

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

Attribute	**Predicate Device** **Optima CT660** (K131576)	**Proposed Device** **Auto Positioning**
Exam Setup Workflow	Manual workflow to set the landmark, patient centering, the scout's start and end locations, and the scout's start table position.	Automated workflow to set the landmark, patient centering, the scout's start and end locations, and the scout's start table position. Addional, automatic safety checks for patient orientation and patient/gantry collision.
Use of Deep Learning for exam set up	The manual workflow for exam setup does not utilize deep learning.	Auto Positioning uses Deep Learning CNNs to determine the scout's landmark location and the patient orientation based on the standard outputs from the 2D/3D camera and the information in the user selected protocol.
Hardware Needed to Support the	Manual patient positioning does not require any unique hardware beyond the what are on the CT system.	The Auto Positioning feature requires a ceiling mounted, off the shelf 2D/3D camera and requires a compatible gantry

Patient Positioning	The hardware used for manual positioning includes: gantry alignment lasers, table motion control switches on the gantry, table, and operator console.	touchscreen In corporation of the Auto Positinoing feature does not remove or disable any of the functionalities for manual patient positioning.
Patient Population	All ages	All ages
Environment of Use	Hospitals, outpatient clinics, research institutions, and other clinical facilities.	Hospitals, outpatient clinics, research institutions, and other clinical facilities.

Risk Analysis:

Potential electrical and mechanical 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 and certification to industry and international standards. (UL/CSA and IEC60601-1 Ed.3.1 and associated collateral and particular standards for CT).

The device is designed and manufactured under the Quality System Regulations of 21 CFR 820 and ISO 13485.

Testing Summary:

The Auto Positioning feature is developed and tested under the same design controls processes, software development life cycle, risk management, and GE quality system as the predicate. Additional engineering bench testing in support of this submission. All testing was successfully completed without unexpected results.

Subsystem verification, system verification, and validation testing including hazard mitigation has been performed with their results demonstrating the Auto Positioning feature meets its design inputs and user needs. Auto Positioning meets the requirements IEC60601-1 Ed. 3.1 and its associated collateral and particular standards.

No new hazards were identified. New causes and mitigations were identified, and their impacts were fully tested without unexpected results. Auto Positioning was designed and will be manufactured under the Quality System Regulations of 21CFR 820 and ISO 13485.

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

- Risk Analysis
- Required Reviews
- Design Reviews

- Software Development Lifecycle
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

GE believes the Auto Positioning system is of comparable type and substantially equivalent to currently marketed system GE Optima CT660(K131576).

The substantial equivalence was also based on software documentation for a "**Moderate**" level of concern device.

Summary of Additional Testing

Non-Clinical Testing:

The verification and validation testing have been successfully completed as required by design control procedures under GE Healthcare's quality system. This includes risk management and, software verification and validation testing.

Because Auto Postioning is for the exam setup process up to the initiation of the first scout scan, and does not involve diagnostic imaging or diagnostic evaluation, non-clinical bench testing is appropriate. This testing included evaluation of the accuracy of the landmark location and the scout scan's start and end location. All testing met its predefined acceptance criteria.

Clinical Testing:

The Auto Positioning can be fully tested on the engineering bench thus no additional clinical testing was required.

Determination of Substantial Equivalence

The Substantial Equivalence of the proposed device has been demonstrated by:

- Review of the proposed Indications for Use shows that it is substantially equivalent to the predicate. Auto Positioning's Indications for Use do not create a new Intended Use.
- The device description and the comparison of device characteristics show that Auto Positioning does not alter energy type, operating principles, or primary control mechanisms as compared to the predicate device.
- The bench testing demonstrates the effectivity of Auto Positioning for its use as a streamlined, alternate CT exam setup workflow.

- The integration of Auto Positioning does not change the IEC standards or 21CFR1020.30 & .33 compliance of the host CT system. The unmodified host CT system's alignment lasers remain available with the Auto Positioning feature.
- The different technological characteristics do not raise new or different questions of safety and effectiveness. The proposed device is as safe and effective as the legally marketed predicate device as demonstrated by the:
  - software verification and validation without unexpected results;
  - development under GE's quality management system, design control activities including risk management
  - device labeling ; and
  - engineering bench testing without unexpected results.

Substantial Equivalence Conclusion:

Auto Positioning's Indications for Use do not create a new Intended Use. Auto Positioning has identical or equivalent technological characteristics as its predicate device and the Siemens' reference device. There is no impact on energy type, operating principles, or primary control mechanisms.

The Auto Positioning was developed under GE Healthcare's quality system. Design verification, along with bench testing included demonstrate that Auto Positioning is substantially equivalent and hence as safe and as effective as the legally marketed predicate and reference devices. GE's quality system's design, verification, and risk management processes did not identify any new hazards, unexpected results, or adverse effects stemming from the changes to the predicate.

Based on development under GE Healthcare's quality system, the successful verification testing and engineering bench testing, GE Healthcare believes that Auto Positioning is substantially equivalent to the predicate device (K131576) and the similar functionality on the Siemens reference device (K173630), and hence is safe and effective for its intended use.