October 24, 2019

GE Hangwei Medical Systems Co.,Ltd.
% Haibo He
Regulatory Affairs Leader
West Area of Building No.3, No.1 Yongchang North Road
Economic and Technological Development
Area, Beijing 100176
CHINA

Re: K192686
Trade/Device Name: Revolution Maxima
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: September 25, 2019
Received: September 26, 2019

Dear Haibo He:

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,

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

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)*

K192686

Device Name
Revolution Maxima

Indications for Use *(Describe)*

The system is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data taken at different angles and planes, including Axial, Cine, Helical (Volumetric), Cardiac, and Gated acquisitions. These images may be obtained either with or without contrast. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories.

This device may include data and image processing to produce images in a variety of trans-axial and reformatted planes. Further the images can be post processed to produce additional imaging planes or analysis results.

The system is indicated for head, whole body, cardiac and vascular X-ray Computed Tomography applications in patients of all ages.

The device output is a valuable medical tool for the diagnosis of disease, trauma, or abnormality and for planning, guiding, and monitoring therapy.

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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GE Healthcare

510(k) Premarket Notification Submission for Revolution Maxima

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:	September 25, 2019
Submitter:	GE Hangwei Medical Systems 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:	Haibo He Regulatory Affairs Leader GE Healthcare Phone Number: (86)-10-57083413 e-mail: Haibo.he1@ge.com
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	Helen Peng Sr Regulatory Affairs Director GE Healthcare Phone Number: 262-4248222 e-mail: hong.peng@ge.com
Product Identification	Revolution Maxima
Device Trade Name: Common/Usual Name:	Revolution Maxima Revolution Ace
Regulation Number / Classification:	Computed Tomography X-ray System, 21 CFR 892.1750 / Class II

Product Code:	90-JAK
Manufacturer	GE Hangwei Medical Systems Co.,Ltd. West Area of Building No.3, No.1 Yongchang North Road, Beijing Economic and Technological Development Area, BEIJING 100176 CHINA
Predicate Device Information:	
Device Name	Optima CT660
510 (K) number	K131576 cleared on August, 2013
Regulation Number/ Classification	Computed Tomography X-ray System, 21 CFR 892.1750 / Class II
Product Code	90-JAK

Marketed Devices:

The Revolution Maxima is a CT device built upon the existing technologies 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. In addition, the system has the same intended use and indication for use as that of the predicate device. The system is labeled as the Revolution Maxima, with an alternate name Revolution Ace.

Device Description:

The Revolution Maxima CT system is composed of a gantry, patient table, operator console, host computer, and power distribution unit (PDU), and interconnecting cables. The system also includes image acquisition and reconstruction hardware/software, general system software, accompanying documents, and associated accessories, interconnections. The Revolution Maxima system is an evolutionary configuration of the predicate Optima CT660 CT system (K131576). All of the hardware functionality is identical to the predicate, however, some hardware changes have been made that did not change the system's performance specifications such as the new liquid metal bearing tube for improved tube life and reliability, the upgraded DAS and detector to improve the manufacturability and lower electronic nosie for better low signal performace and thermal management.

Identical to the predicate, Revolution Maxima generates cross-sectional images of the body by computer reconstruction of x-ray transmission data taken at different angles and planes,

including Axial, Cine, Helical (Volumetric), Cardiac, and Gated acquisitions modes. Revolution Maxima's Intended Use and Indications for Use remain identical to those of the predicate device.

The Revolution Maxima CT system is a head and whole body CT system incorporating the same basic fundamental operating principles and the same indications for use as the predicate device. It's materials and construction are identical to our existing marketed products. Revolution Maxima remains compliant with IEC 60601-1 Ed. 3.1 and associated collateral and particular standards, NEMA XR 25, XR 26, XR 28, and 21 CFR Subchapter J performance standards. The accompanying documents also contain the information in support of IEC61223-3-5 Ed. 1.0 for acceptance testing.

The performance and image quality specifications are identical/equivalent to the predicate. The gantry has a 70 cm bore with a maximum FOV of 50 cm. Available rotation speeds range from 0.35 to 2.0 seconds. Same as the predicate, the Revolution Maxima has three types of reconstruction methods available: FBP, ASiR, and ASiR-V (K133640). The performance of ASiR-V on Revolution Maxima is identical to that on the predicate Optima CT660.

Revolution Maxima includes most of the available features on the current production predicate device Optima CT660. The new changes incorporated into Revolution Maxima are primarily addition of a few features found on other GE current production CT systems, e.g. updated newer ITE host computer, Digital Tilt as an alternative to the tilted gantry, improved metal artifacts reduction called Smart MAR and 1024x1024 Recon. Digital Tilt is a software reformatting of the reconstructed images so that they appear like those reconstructed from a tilted gantry. The smaller pixel sizes of 1024 Recon improves the spatial resolution which is useful in clinical applications that would benefit from increased spatial resolution, especially those applications where a large display field of view is desired to simultaneously image corresponding left/right anatomy for comparison (e.g. high-resolution lungs, internal auditory canals).

There are other unique changes for Revolution Maxima which includes new gantry covers with more aesthetic and modern industry design, new gantry display panel on two tablets with high resolution touchscreens, one on each side of the gantry for improved access and usability. These gantry display tablets replace the single display screen located at the top center of the gantry in the predicate device and host the web based user interface for a new and improved workflow called "Express mode" which seamlessly displays the related protocols associated with order information in the RIS

Intended Use:

The system is intended to be used for head, whole body Computed Tomography applications.

Indications for Use:

The system is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data taken at different angles and planes, including Axial, Cine, Helical (Volumetric), Cardiac, and Gated acquisitions. These images may be obtained either with or without contrast. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories.

This device may include data and image processing to produce images in a variety of trans-axial and reformatted planes. Further the images can be post processed to produce additional imaging planes or analysis results.

The system is indicated for head, whole body, cardiac and vascular X-ray Computed Tomography applications in patients of all ages.

The device output is a valuable medical tool for the diagnosis of disease, trauma, or abnormality and for planning, guiding, and monitoring therapy.

Technology:

Revolution Maxima includes most of the available features on the current production predicate device Optima CT660 and employs the same fundmental technologies as those of the predicate device. The changes incorporated into Revolution Maxima are primarily addition of a few features found on other GE current production CT systems, e.g. updated newer host computer, There are other unique changes for Revolution Maxima which are primarily for new industry design, IQ improvement, and workflow optimization. These include new gantry covers, new gantry display panel with two tablets located on both sides of the gantry with web based UI to auto display related protocols associated with order information in the RIS.

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

Subsystem	Predicate Device Optima CT660 (K131576)	Proposed Device Revolution Maxima
Gantry Display Panel	Gantry Display - Video touchscreen on top center of gantry - Emergency patient exam - Display gantry and table position information. - Display multiple system status. - Display patient and exam information. - Display Patient ECG waveform. - Default Patient Positioning (DPP). - Play movie.	Gantry Display "Xtream Tablet" (the "tablet" is not removable) - **HD Video touchscreen on each side of gantry** - New-Patient/Emergency Patient exam. - Display gantry and table position information. - Display multiple system status. - Display patient and exam information. - Display Patient ECG waveform. - Default Patient Positioning (DPP). - Play movie.
1024x1024 Image Recon	Not Available	Available
Related Protocols	Not Available	Available
Smart MAR	Not Available	Available
Tilt	Physical tilt	Digital Tilt

The changes described above do not change the fundamental control mechanism, operating principle, energy type, and do not change the intended use from the predicate device Optima CT660.

Risk Analysis:

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 and certification to industry and international standards. (UL/CSA and IEC60601-1 Ed.3.1 and associated collateral and particular standards for CT).
- Compliance to applicable CDRH 21 CFR subchapter J requirements.
- Compliance to NEMA XR 25, XR 26, and XR 28.

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

Determination of Substantial Equivalence:

The Revolution Maxima has completed testing and in compliance with AAMI/ANSI ES 60601-1 and IEC60601-1 Ed. 3.1 and its associated collateral and particular standards, 21 CFR Subchapter J, and NEMA standards XR 25, XR 26, and XR 28. The device has successfully completed all testing per our quality system as well as addition engineering bench testing in support of this submission. It was designed and is manufactured under the Quality System Regulations of 21 CFR 820 and ISO 13485. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Required Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

GE believes the Revolution Maxima system is of comparable type and substantially equivalent to our currently marketed system 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, software verification and validation testing as well as image quality and dose performance using standard IQ and QA phantoms, such as Metal artifact

reduction(MAR) testing, image quality testing on 1024 Recon and the performance testing in accordance with IEC 61223-3-5 ed 2 (FDIS).

Non-clinical bench test results demonstrated the subject device performs equivalently to the predicate device.

Clinical Testing:

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

Substantial Equivalence Conclusion:

Based on the conformance to standards, development under our quality system, and the engineering testing provided, GE Healthcare believes that the Revolution Maxima is as safe and effective, and performs in a substantially equivalent manner to the predicate device Optima CT660 (K131576).