DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

June 5, 2017

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

Re: K171013
Trade/Device Name: Revolution ACT
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: April 5, 2017
Received: April 6, 2017

Dear Wang Xing:

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,

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

Section 4: Indications for Use Statement

Revolution ACT

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)*
K171013

Device Name
Revolution ACT

Indications for Use *(Describe)*
The GE Revolution ACT Computed Tomography X-ray 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, for patients of all ages, including Axial, Cine, Helical.

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 GE Revolution ACT CT Scanner System is indicated for head, whole body and vascular X-ray Computed Tomography applications.

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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Section 5: 510(k) Summary

Revolution ACT

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:	March 31, 2017
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:	Wang Xing Regulatory Affairs Manager GE Healthcare Phone Number: (86)-10-57388271 e-mail: xing1.wang@ge.com
Secondary Contact Persons:	John Jaeckle Chief Regulatory Affairs Strategist GE Healthcare Phone Number: 262-424-9547 e-mail: John.Jaeckle.com
	Tracey Fox Regulatory Affairs Director GE Healthcare Phone Number: 262-337-2586 e-mail: tracey.fox@ge.com
Product Identification	Revolution ACT
Device Trade Name: Common/Usual Name:	Revolution ACT / Revolution ACTs Computed Tomography X-ray System
Classification Names: Product Code:	Computed Tomography X-ray System, 21 CFR 892.1750 (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
Manufacturing location(s)	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

Predicate Device:

Optima CT520 - K123596

Marketed Devices:

The Revolution ACT is a CT device built upon the existing technologies of the predicate device, GE Healthcare' s currently marketed Computed Tomography X-ray System Optima CT520 (K123596). It is of comparable type and substantially equivalent to Optima CT520. In addition, the system has the same intended use and indication for use as that of the predicate device except the cardiac and gated acquisition indications are removed. The system is labeled as the Revolution ACT.

Device Description:

The multi-slice GE Revolution ACT CT scanner is currently commercially available and in clinical use in various other countries including the EU, Japan, China, and India.

It is a general purpose, 16-slice (detector row) CT scanning system with a z-coverage of 20 mm and a maximum gantry rotation speed of 0.98 seconds. Revolution ACT is designed to help enable greater patient access to CT imaging in facilities that otherwise might not be able to obtain multi-slice CT technology with both current standard and advanced CT features and function.

Revolution ACT uses the same technology, operating principles, features, and functions as the GE Optima CT520 predicate device (K123596) and other cleared GE CT scanners. The system consists of the gantry, patient table, operator console, power distribution unit (PDU), associated accessories, and software options. The Revolution ACT is also available in an 8-detector row (10 mm z-coveragre configuration (Revolution ACTs) using the identical (but depopulated) detector/DAS. The changes from the predicate device do not affect the intended use or patient population.

Becaues the Revolution ACT does not support cardiac or other gated acquisitions, and has a slower rotation time thatn the predicate device, its indications for use were modified by removing cardiac and gated acquisitions and cardiac applications.

Revolution ACT complies with the current IEC 60601-1 Edition 3.1 series of standards (IEC 60601-1-2, 60601-1-3, 60601-2-28, and 60601-2-44), NEMA XR-25, XR-26, and XR-28, and 21 CFR 1020.30 and 1020.33. The materials are the same as those used on other cleared GE CT systems. It has been developed under the GE quality system and has successfully completed design controls activities, including risk management, verification, and validation.

The Revolution ACT is a head and whole body CT system. The device has the same intended use as predicate device Optima CT520 except cardiac and gated acquisition indications are removed. There are no new intended uses for Revolution ACT beyond those of the predicate.

Intended Use:

The GE Revolution ACT CT Scanner System is indicated for head, whole body and vascular X-Ray Computed Tomography applications

Indications for Use:

The GE Revolution ACT Computed Tomography X-ray 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, for patients of all ages, including Axial, Cine, Helical.

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 GE Revolution ACT CT Scanner System is indicated for head, whole body and vascular X-ray Computed Tomography applications

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

Technology:

The Revolution ACT has a redesigned gantry and new image change components. The gantry has a maximum rotation speed of 0.98 seconds, a 65 cm bore, no physical tilt, and a smaller footprint and lower power needs for easier siting. It incorporates a lower power, single focal spot X-ray tube that is used on other GE systems, and has a redesigned detector that supports a smaller (43 cm) field of view. The detector continues to use GE's

HiLight scintillator. Revolution ACT maintains virtually the same image quality specifications and dose performance as its predicate.

Most the software features and functions are common between the Revolution ACT and its predicate, the others, except for SmartPlan, are available on other cleared GE CT scanners. SmartPlan is designed for workflow enhancement by providing the operator with initial scan set up paraments, such as scan Start and End location, derived from the scout images.

The changes described above do not change the fundamental control mechanism, operating principle, energy type, and do not change the intended use from the currently commercially available predicate device Optima CT520.

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 21CFR subchapter J requirements.
- Compliance to NEMA XR-25, XR-26, and XR28.

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

Determination of Substantial Equivalence:

The Revolution ACT 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, 21CFR Subchapter J, and NEMA standards XR25, XR26, and XR28. 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 21CFR 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 ACT system is of comparable type and substantially equivalent to our currently marketed system Optima CT520.

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

Summary of Additional Testing

Non-Clinical Testing:

In addition to the verification and validation testing successfully completed as required by GE Healthcare's quality system, additional engineering bench testing was performed. The test were chosen to provide a broad base of system performance testing that is relevant to demonstrating Revolution ACT's ability for safe and effective diagnostic CT imaging. Because of the basic nature (existing technology and features) of Revolution ACT, no new metrics or test methods were needed for the bench testing evaluations.

The additional engineering testing performed included performance testing related to Revolution ACT's ability to scan large patients, the performance tests in accordance with IEC 61223-3-5, and testing of the new SmartPlan feature.

A comparision of: CT number accuracy; CT number uniformity; Image noise (standard deviation); Modulation Transfer Function; Noise Power Spectrum; and Slice thickness between the predicate and subject device was provided.

Images from both a uniform phantom and one with embedded LCD objects were provided for the subject device using several reconstruction techniques.

Additionally provided was a description of the process used to port ASiR onto the new hardware of the subject device.

Clinical Testing:

The type of design changes and having features and functions that are found on the predicate device and other cleared GE CT systems, support using scientific, established, standardized engineering/physics-based verification and performance testing to demonstrate that the device is as safe and as effective as the predicate device.

However, to provide further verification that the previously cleared iterative reconstruction algorithm worked on the modified hardware platform, sample clinical images reviewed by a board certified radiologist were provided.

There are several hundred Revolution ACT systems installed globally. The device (both 16 and 8-slice configurations) have been in commercial use for clinical diagnosis and its performance and image quality has been demonstrated to be diagnostically acceptable.

Substantial Equivalence Conclusion:

Given that:

- The updated Indications for Use fall within the indicatons for use, and the changes do not represent any new intended uses.
- RevolutionACT has been tested and certified to comply with the above indentifed standards. And development under our quality system.
- Verification testing along with additional engineering testing demonstrated Revolution ACT's equivalent performance to currently marketed the predicate and other cleared GE CT devices and is therefore as safe and effective.
- The changes and the verification, validation, and additional engineering testing did not raise new or different questions of safety and effectiveness, and no new hazards were created.

GE Healthcare believes that the Revolution ACT is as safe and effective for its intended use, and performs in a substantially equivalent manner to the predicate device, Optima CT520