September 17, 2021

GE Healthcare Japan Corporation
% Katelyn Rowley
Regulatory Affairs Leader
GE Medical Systems, LLC
3000 North Grandview Blvd.
WAUKESHA WI 53188

Re: K212067
Trade/Device Name: Deep Learning Image Reconstruction
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: August 27, 2021
Received: August 30, 2021

Dear Katelyn Rowley:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212067

Device Name
Deep Learning Image Reconstruction

Indications for Use *(Describe)*
The Deep Learning Image Reconstruction software is a deep learning based reconstruction method intended to produce cross-sectional images of the head and whole body by computer reconstruction of X-ray transmission data taken at different angles and planes, including Axial, Helical (Volumetric), and Cardiac acquisitions, for all ages.
Deep Learning Image Reconstruction software can be used for head, whole body, cardiac, and vascular CT applications.

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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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):

Date:	July 01, 2021
Submitter:	GE Healthcare Japan Corporation 7-127, Asahigaoka, 4-chome Hino-shi, Tokyo, 191-8503, Japan
Primary Contact:	Katelyn Rowley Regulatory Affairs Leader Phone 262-309-5888 Email: Katelyn.rowely@ge.com
Secondary Contacts:	Helen Peng Senior Regulatory Affairs Director GE Healthcare Tel: 262-424-8222 Email: hong.peng@med.ge.com John Jaeckle Chief Regulatory Affairs Strategist GE Healthcare Tel: 262-424-9547 Email: john.jaeckle@med.ge.com
Device Trade Name:	Deep Learning Image Reconstruction
Device Classification	Class II
Regulation Number/ Product Code:	21 CFR 892.1750 Computed tomography x-ray system / JAK

Predicate Device Information

Device Name:	Deep Learning Image Reconstruction
Manufacturer:	GE Medical Systems, LLC
510(k) Number:	K193170 cleared on December 13, 2019
Regulation Number/ Product Code:	21 CFR 892.1750 Computed tomography x-ray system / JAK

Reference Devices Information

Device Name:	ASiR-V
Manufacturer:	GE Medical Systems, LLC
510(k) Number:	K133640 cleared on March 25, 2014
Regulation Number/ Product Code:	21 CFR 892.1750 Computed tomography x-ray system / JAK

Device Name:	Revolution Ascend
Manufacturer:	GE Healthcare Japan Corporation
510(k) Number:	K203169 cleared on March 20, 2020
Regulation Number/ Product Code:	21 CFR 892.1750 Computed tomography x-ray system / JAK

Device Description

Deep Learning Image Reconstruction is an image reconstruction method that uses a dedicated Deep Neural Network (DNN) that has been designed and trained specifically to generate CT Images to give an image appearance, as shown on axial NPS plots, similar to traditional FBP images while maintaining the performance of ASiR-V in the following areas: dose, image noise (pixel standard deviation), low contrast detectability, high-contrast spatial resolution, and streak artifact suppression.

The images produced are branded as "TrueFidelity™ CT Images". Reconstruction times with Deep Learning Image Reconstruction software support a normal throughput for routine CT.

The deep learning technology is integrated into the scanner's existing raw data-based image reconstruction chain to produce DICOM compatible "TrueFidelity™ CT Images".

The system allows user selection of three strengths of Deep Learning Image Recon: Low, Medium or High. The strength selection will vary with individual users' preferences and experience for the specific clinical need.

Deep Learning Image Reconstruction software was initially introduced on the Revolution CT systems (K133705, K163213). Subsequently, it was introduced on the Revolution EVO system (K131576) and cleared in December 2019 with K193170. The DLIR algorithm is now being ported, without retraining, to Revolution Ascend (K203169), thus triggering this premarket notification.

Compared to the predicate device, the intended use and indications for use of Deep Learning Image Reconstruction are identical.

Intended Use

The Deep Learning Image Reconstruction software is intended for head, whole body, cardiac, and vascular CT Scans.

Indications for Use

The Deep Learning Image Reconstruction software is a deep learning based reconstruction method intended to produce cross-sectional images of the head and whole body by computer reconstruction of X-ray transmission data taken at different angles and planes, including Axial, Helical (Volumetric), and Cardiac acquisitions, for all ages.

Deep Learning Image Reconstruction software can be used for head, whole body, cardiac, and vascular CT applications.

Comparisons

The GE Deep Learning Image Reconstruction (DLIR) software for the Revolution Ascend is substantially equivalent to the unmodified predicate device DLIR reconstruction option for Revolution EVO CT systems. The fundamental technology, i.e the DLIR algorithm, remains unchanged from the predicate. The table below summarizes the substantive feature/technological differences between the predicate device and the proposed device:

Specification/ Attribute	**Deep Learning Image Reconstruction** **(Predicate Device, K193170)**	**Deep Learning Image Reconstruction** **(Proposed Device)**
Technology	Utilizes a dedicated Deep Neural Network (DNN) which was trained on the Revolution family CT Scanners and designed specifically to generate high quality CT images	Same
Clinical Workflow	Select recon type and strength (Low, Medium, High).	Same
Clinical Use	Routine Clinical Use	Same
Reference protocols/dose	Using the same Reference protocols provided on the **Revolution EVO** system for ASiR-V	Using the same Reference protocols provided on the **Revolution Ascend** system for ASiR-V
IQ performance vs dose	Image noise, low contrast detectability, spatial resolution, and low signal artifact suppression as good or better than ASiR-V on **Revolution EVO**	Image noise, low contrast detectability, spatial resolution, and low signal artifact suppression as good or better than ASiR-V on **Revolution Ascend**
Deployment Environment	On GE's Edison Platform.	Same

Deep Learning Image Reconstruction as deployed on the Revolution Ascend CT System does not introduce any new risks/hazards, warnings, or limitations.

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

Determination of Substantial Equivalence

Summary of Non-Clinical Testing

Deep Learning Image Reconstruction has successfully completed the design control testing per our quality system. No additional hazards were identified, and no unexpected test results were observed. Deep Learning Image Reconstruction was designed under the Quality System

Regulations of 21CFR 820 and ISO 13485. GE believes that the extensive bench testing and the physician evaluation are sufficient for FDA's substantial equivalence determination.

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

- Requirement Definition
- Risk Analysis and Control
- Technical Design Reviews
- Formal Design Reviews
- Software Development Lifecycle
    - Code Review
    - Software Unit Implementation
    - Software Integrations and Integration Testing
- System Testing
    - Safety Testing (Verification)
    - Image Performance Testing (Verification)
    - Simulating Use Testing (Validation)
- Software Release

The testing and results did not raise different questions of safety and effectiveness than associated with predicate device. We consider the proposed device is substantially equivalent to the predicate device, DLIR.

The substantial equivalence is also based on the software documentation for a "Moderate" level of concern.

Additional Non-Clinical Testing

Engineering bench testing was performed to support substantial equivalence and the product performance claims. The evaluation and analysis used the identical raw datasets obtained on GE's Revolution Ascend CT systems and then applies the Deep Learning Image Reconstruction or ASiR-V reconstruction. The resultant images were then compared for:

- Low contrast detectability (LCD)
- Image Noise (pixel standard deviation)
- High contrast spatial resolution (MTF)
- Streak Artifact Suppression
- Spatial Resolution
- Noise Power Spectrum (NPS) and Standard Deviation of noise
- CT Number Accuracy and Uniformity
- Contrast to Noise (CNR) ratio
- Artifact analysis – metal objects, unintended motion, truncation
- Pediatric Image Quality Performance
- Low Dose Lung Cancer Screening

Clinical Testing

The reader study used a total of 60 retrospectively collected clinal cases. The raw data from each of these cases was reconstructed with both ASiR-V and Deep Learning Image Reconstruction and presented to each reader independently. The results of the study support substantial equivalence and performance claims.

These images were read by 9 board-certified radiologists with expertise in the specialty areas that align with the anatomical region of each case. Each image was read by 3 different radiologists who provided an assessment of image quality related to diagnostic use according to a 5-point Likert scale. Additionally, the readers were asked to compare directly the ASiR-V and Deep Learning Image Reconstruction images according to the key metric of image noise texture and image sharpness. The readers completed their evaluations independently and were blinded to the results of the other readers' assessments.

Substantial Equivalence

The changes associated with Deep Learning Image Reconstruction do not change the Intended Use from the predicate, and represent equivalent technology, with no impact on control mechanism, operating principle, or energy type.

Deep Learning Image Reconstruction (DLIR) software for Revolution Ascend was developed under GE Healthcare's quality system. Design verification, validation along with bench testing and the clinical reader study demonstrate that the Deep Learning Image Reconstruction (DLIR) software is substantially equivalent and hence as safe and as effective as the legally marketed predicate device. GE's quality system's design, verification, validation, 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 and validation testing, including the additional engineering bench testing, and the clinical reader study, GE Healthcare believes that Deep Learning Image Reconstruction Software is substantially equivalent to the predicate device and hence is safe and effective for its intended use.