February 18, 2022

GE Medical Systems, LLC.
% Amy Yang
Regulatory Affairs Manager
3000 N. Grandview Blvd.
WAUKESHA WI 53188

Re: K213999
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: December 20, 2021
Received: December 21, 2021

Dear Amy Yang:

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,

Laurel Burk
Assistant Director
Diagnostic X-ray Systems Team
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

K213999

Section 4: Indications for Use Statement

Deep Learning Image Reconstruction (DLIR)

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)*

K213999

Device Name
Deep Learning Image Reconstruction

Indications for Use *(Describe)*

The Deep Learning Image Reconstruction option 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 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 OF SAFETY AND EFFECTIVNESS K213999

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirement of 21 CFR Part 807.92:

Date:	December 20, 2021
Submitter:	GE Medical Systems, LLC 3000 North Grandview Blvd Waukesha, WI 53188
Primary Contact:	Amy Yang Regulatory Affairs Manager GE Healthcare Phone: 1-414-514-3904 Email: amy.yang@ge.com
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Subject Device 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:	K183202 cleared on April 12, 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:	K134640 cleared on March 25, 2014
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: 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 support a normal throughput for routine CT.

Deep Learning Image Reconstruction was trained specifically on the Revolution CT/Apex platform (K163213, K133705, K191777). 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.

The DLIR algorithm is now being modified on the Revolution family CT systems (K133705, K163213, K191777) for improved reconstruction speed and image quality, 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 option is intended for head, whole body, cardiac, and vascular CT scans.

Indications for Use

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

Comparisons

The modified Deep Learning Image Reconstruction (DLIR) option is substantially equivalent to the predicate device K183202. The modified DLIR is based on the same fundamental technology as the predicate device and is implemented on the Revolution CT/Apex platform (K133705, K163213, K191777). They utilize the same hardware and software platform technology on which substantial equivalence is demonstrated. The table below summarizes the substantive feature/technological similarities and differences between the predicate device and the proposed device:

Specification/ Attribute	**Predicate Device** DLIR for Revolution CT (K183202)	**Proposed Device** Modified DLIR for Revolution CT/Apex platform
Technology	DLIR uses a dedicated Deep Neural Network (DNN) which is trained on the CT scanner and therefore models the propagation of noise through the system to identify and remove the noise	Same DNN technology with revised network architecture with retraining and inferencing techniques
System statistics - Noise modeling of the data collection imaging chain (photon noise and electronic noise)	Characterization of the photon statistics as it propagates through the preprocessing and calibration imaging chain	Same
System statistics – Noise characteristics of the reconstructed images	DLIR uses a trained DNN which models the scanned object using information obtained from extensive phantom and clinical data to identify the noise characteristics and remove it	Same
Clinical Workflow	Select recon type and strength (Low, Medium, High).	Same

The subject device Deep Learning Image Reconstruction does not introduce any additional risks/hazards, warnings, or limitations.

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 same test methodologies and acceptance criteria with the identical raw datasets obtained on GE's Revolution CT/Apex platform and then applying the Deep Learning Image Reconstruction or ASiR-V reconstruction (hence the dose (CTDIvol) is identical for both). 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, longitudinal (FWHM slice sensitivity profile)
- Noise Power Spectrum (NPS) and Standard Deviation of noise
- CT Number Uniformity

- CT Number Accuracy
- Contrast to Noise (CNR) ratio
- Artifact analysis – metal objects, unintended motion, truncation
- Pediatric Phantom IQ Performance Evaluation
- Low Dose Lung Cancer Screening Protocol IQ Performance Evaluation

Clinical Testing

The reader study used a total of 40 retrospectively collected clinical cases. The raw data from each of these cases was reconstructed with both ASiR-V and Deep Learning Image Reconstruction and presented side by side to each reader independently. The results of the study support substantial equivalence and performance claims.

These images were read by 6 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. Three readers read the cases primarily covering body and extremity anatomy, and three different readers read the cases primarily covering neuro anatomy.

Additionally, the readers were asked to compare directly the ASIR-V and Deep Learning Image Reconstruction images according to three key metrics of image quality preference – image noise texture, image sharpness, and image noise texture homogeneity.

The result of this reader study confirmed that the DLIR (the subject device) produce diagnostic quality images and have significantly better subjective image quality than the corresponding images generated with the ASiR-V reconstruction algorithm.

Substantial Equivalence

The changes associated with Deep Learning Image Reconstruction do not change the Intended Use or indications for use from the predicate, and represent equivalent technological characteristics including the dedicated neural network, with no impact on control mechanism or operating principle.

Deep Learning Image Reconstruction was developed under GE Healthcare's quality system. Design verification, along with bench testing and the clinical reader study provided in this submission demonstrates that modified Deep Learning Image Reconstruction is substantially equivalent and hence as safe and as effective as the legally marketed predicate device. GE's quality system's design, verification, and risk management processes did not identify any additional hazards, unexpected results, or adverse effects stemming from the changes to the predicate.

GE Healthcare believes that Deep Learning Image Reconstruction is substantially equivalent to the predicate device and hence is safe and effective for its intended use.