GE Healthcare Japan Corporation   December 13, 2019
℅ Ms. Helen Peng
Sr. Regulatory Affairs Director
GE Medical Systems, LLC
3000 North Grandview Blvd.
WAUKESHA WI 53188

Re: K193170
     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: November 14, 2019
     Received: November 15, 2019

Dear Ms. Peng:

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: 06/30/2020

See PRA Statement below.

510(k) Number *(if known)*

K193170

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.

K193170

<u>510(k) SUMMARY OF SAFETY AND EFFECTIVNESS</u>

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

Date:	November 14, 2019
Submitter:	GE Healthcare Japan Corporation
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	Hino-shi, Tokyo, 191-8503, Japan
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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

<u>Predicate Device Information</u>

Device Name:	Deep Learning Image Reconstruction
Manufacturer:	GE Medical System SCS (d.b.a GE Healthcare)
510(k) Number:	K183202 cleared on April 12, 2019
Regulation Number/ Product Code:	21 CFR 892.1750 Computed tomography x-ray system / JAK

<u>Reference Device Information</u>

Device Name:	ASiR-V
Manufacturer:	GE Medical System SCS (d.b.a GE Healthcare)
510(k) Number:	K133640 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^{TM} 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^{TM} 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). The DLIR algorithm is now ported to Revolution EVO (K131576), which offers 64 detector row and up to 40mm collimation, and ASIR-V reconstruction option.

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 software for the Revolution EVO is substantially equivalent to the unmodified predicate device DLIR reconstruction option for Revolution family of 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, (K183202)	Deep Learning Image Reconstruction (Proposed Device)
Technology	Utilizes a dedicated Deep Neural Network (DNN) which is trained for the Revolution family CT Scanners and designed specifically to generate high quality CT images	Same
Clinical Workflow	Select recon type and strength (High, Medium, Low)	Same
Clinical Use	Routine Clinical Use	Same
Reference protocols/dose	Using the same Reference protocols provided on the Revolution CT system for ASiR-V	Using the same Reference protocols provided on the Revolution EVO 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 CT	Image noise, low contrast detectability, spatial resolution, and low signal artifact suppression as good or better than ASiR-V on Revolution EVO.
Deployment Environment	On CT console	On GE's Edison Platform.

Deep Learning Image Reconstruction algorithm itself 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 software has successfully completed the design control testing per our quality system. No new hazards were identified, and no unexpected test results were obtained. Deep Learning Image Reconstruction was designed under the Quality System Regulations of 21CFR 820 and ISO 13485. GE believes that the extensive software testing, IQ

bench testing, and the clinical reader study evaluation are sufficient for FDA's substantial equivalence determination.

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

- Risk Analysis and Control
- Requirement Reviews
- Design Reviews
- Software Development Lifecycle
- Verification Testing at unit, integration and system levels
- Design Validation Resting

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 for Revolution CT family of products.
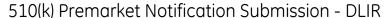
The substantial equivalence is also based on the software documentation for a "Moderate" level of concern device

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 EVO CT System and then applies the Deep Learning Image Reconstruction (DLIR) or ASiR-V reconstruction (hence the dose (CTDIvol) is identical for both). The resultant images were then compared for:

- Low Contrast Detectability (LCD) using the head and body MITA/FDA low contrast phantoms and a model observer
- Low Contrast Detectability (LCD) with statistical method
- Image Noise (pixel standard deviation) using both head and body uniform phantoms
- High-Contrast Spatial Resolution (MTF) using a quality assurance phantom with a small diameter tungsten wire surrounded by water inside the phantom to generate the point spread function
- Streak Artifact Suppression using an oval uniform polyethylene phantom with embedded high attenuation objects to produce the artifacts
- Spatial Resolution, longitudinal (FWHM slice sensitivity profile)
- 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 (DLIR) and presented to each reader independently. The results of the study support substantial equivalence and performance claims.

These images were read by 7 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. The readers completed their evaluations independently and were blinded to the results of the other readers' assessments

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

Substantial Equivalence

The changes associated with Deep Learning Image Reconstruction (DLIR) software do not change the Indications for Use from the predicate, and represent equivalent technological characteristics, with no impact on control mechanism, operating principle, and energy type.

Deep Learning Image Reconstruction (DLIR) software for Revolution EVO 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, the additional engineering bench testing, and the clinical reader study, GE Healthcare believes that the Deep Learning Image Reconstruction (DLIR) Software is substantially equivalent to the unmodified predicate device and hence is safe and effective for its intended use.