GE Medical Systems, LLC
℅ Ms. Katelyn Rowley
Regulatory Affairs Leader
3000 N. Grandview Blvd.
WAUKESHA WI 53188

December 10, 2020

Re: K201745
    Trade/Device Name: Deep Learning Image Reconstruction for Gemstone Spectral Imaging
    Regulation Number: 21 CFR 892.1750
    Regulation Name: Computed tomography x-ray system
    Regulatory Class: Class II
    Product Code: JAK
    Dated: November 13, 2020
    Received: November 16, 2020

Dear Ms. 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

Section 4:   Indications for Use

Deep Learning Image Reconstruction for Gemstone Spectral Imaging (GSI_DLIR)

Indications for Use

510(k) Number *(if known)*

K201745

Device Name

Deep Learning Image Reconstruction for Gemstone Spectral Imaging

Indications for Use *(Describe)*

The Deep Learning Image Reconstruction for Gemstone Spectral Imaging option is a deep learning based CT reconstruction method intended to produce cross-sectional images by computer reconstruction of dual energy X-ray transmission data acquired with Gemstone Spectral Imaging, for all ages. Deep Learning Image Reconstruction for Gemstone Spectral Imaging can be used for whole body, vascular, and contrast enhanced head 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.

<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:	June 25, 2020
Submitter:	GE Medical Systems, LLC 3000 North Grandview Blvd Waukesha, WI 53188
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
Device Trade Name:	Deep Learning Image Reconstruction for Gemstone Spectral Imaging
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 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

<u>**Reference Devices Information**</u>

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

Reference Devices Information

Device Name:	Revolution CT
Manufacturer:	GE Medical Systems, LLC
510(k) Number:	K163213 cleared on December 16, 2016
Regulation Number/ Product Code:	21 CFR 892.1750 Computed tomography x-ray system / JAK

Device Description

Deep Learning Image Reconstruction for Gemstone Spectral Imaging (DLIR-GSI) is the next step in CT reconstruction advancement. Like its predicate device (DLIR), DLIR-GSI is an image reconstruction method that uses a dedicated Convolution Neural Network (CNN) that has been designed and trained specifically to reconstruct CT GSI Images to give an image appearance similar to traditional FBP images while maintaining or improving the performance of ASiR-V. The DLIR-GSI can generate monochromatic images (MC), material decomposition images (MD), and virtual unenhanced images (VUE). Multiple MD images such as Iodine, Water, Calcium, Hydroxyapatite (HAP), Fat, Uric Acid can be prescribed by the user and generated by the subject device. DLIR-GSI demonstrates same or better Imaging performance as compared to ASiR-V in the following areas: low contrast detectability (LCD), image noise, contrast to noise ratio (CNR), high contrast spatial resolution, CT number accuracy, MD quantification accuracy and metal artifact reduction. Reconstruction times with DLIR-GSI support a normal throughput for routine CT.

The device is marketed as Deep Learning Image Reconstruction for Gemstone Spectral Imaging and the images produced are branded as "TrueFidelity^{TM} CT Images".

Deep Learning Image Reconstruction for Gemstone Spectral Imaging is compatible with dual energy scan modes using the standard kernel and was trained specifically on the Revolution CT family of systems (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^{TM} CT Images".

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

As compared to the predicate device, the intended use of Deep Learning Image Reconstruction for Gemstone Spectral Imaging does not change (head and whole-body CT image reconstruction). Both algorithms are designed to produce cross-sectional images of the head and body by computer reconstruction of X-ray transmission data, for all ages.

Intended Use

The Deep Learning Image Reconstruction for Gemstone Spectral Imaging option is intended for whole body, vascular, and contrast enhanced head CT applications.

Indications for Use

The Deep Learning Image Reconstruction for Gemstone Spectral Imaging option is a deep learning based CT reconstruction method intended to produce cross-sectional images by computer reconstruction of dual energy X-ray transmission data acquired with Gemstone Spectral Imaging, for all ages. Deep Learning Image Reconstruction for Gemstone Spectral Imaging can be used for whole body, vascular, and contrast enhanced head CT applications.

Comparisons

The Deep Learning Image Reconstruction for Gemstone Spectral Imaging (DLIR-GSI) employs the same fundamental technology as that of the predicate device. In fact, the DLIR-GSI deep learning neural network was modified from that of the predicate. The DLIR-GSI option is substantially equivalent to the predicate device, DLIR reconstruction option. Because both the DLIR-GSI and the predicate device DLIR reconstruction for single energy are implemented on reference device, the Revolution CT family of Systems with GSI (K163213) they utilize the same hardware and software platform technology on which substantial equivalency is demonstrated. The table below summarizes the substantive feature/technological similarities and differences between the predicate device and the proposed device:

Specification/ Attribute	Deep Learning Image Reconstruction (Predicate Device, K183202)	Deep Learning Image Reconstruction for Gemstone Spectral Imaging (Proposed Device)
Compatible Image Types	Compatible with <u>single</u> energy scan modes and standard kernel.	Compatible with <u>dual</u> energy scan modes and standard kernel.
IQ performance vs dose	Low contrast detectability (LCD), image noise, contrast to noise ratio (CNR), and high contrast spatial resolution are as good or better than ASiR-V when substituted using raw data from the same scan.	Same
Technology	Utilizes a dedicated neural network which is trained using <u>single</u> energy acquired images on the CT Scanner and designed specifically to generate high quality CT images.	Utilizes a dedicated neural network which is trained using <u>dual</u> energy acquired images on the CT Scanner and designed specifically to generate high quality CT images.
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	Utilizes a trained neural network which models the scanned object using information obtained from extensive phantom and clinical data.	Same
Clinical Workflow	Select recon type and strength (Low, Medium, High).	Same

Deep Learning Image Reconstruction for Gemstone Spectral imaging does not introduce any additional risks/hazards, warnings, or limitations.

Determination of Substantial Equivalence

Summary of Non-Clinical Testing

Deep Learning Image Reconstruction for Gemstone Spectral Imaging 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 for Gemstone Spectral Imaging 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
- Technical Design Reviews
- Formal Design Reviews
- Code Review
- Software Unit Implementation
- Software Integrations and Integration Testing
- System Testing
    o Safety Testing (Verification)
    o Image Performance Testing (Verification)
    o 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 CT family of systems and then applies the Deep Learning Image Reconstruction for Gemstone Spectral Imaging 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)
- Contrast to noise ratio (CNR)
- CT Number accuracy
- CT Number uniformity
- Material Decomposition accuracy
- Iodine detection

- Metal artifact reduction
- Pediatric test with anthropomorphic phantom

Clinical Testing

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

These images were read by 5 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, three readers read the cases primarily covering contrast enhanced head/neck anatomy. One reader was qualified to read both body and head/neck anatomy.

Additionally, the readers were asked to compare directly the ASiR-V and Deep Learning Image Reconstruction for Gemstone Spectral Imaging images according to the key metric of image noise texture.

The result of this reader study confirmed that the DLIR-GSI (the subject device) produce diagnostic quality images and have preferred noise texture than the reference device ASiR-V.

To further challenge the DLIR-GSI reconstruction algorithm, 7 additional retrospectively collected clinically challenging cases containing small, low contrast objects were evaluated. These images were read by a board-certified radiologist with expertise in the specialty area that aligns with all cases. The reader confirmed that all object(s) were adequately visualized for diagnostic use using DLIR-GSI. This additional clinical evaluation further confirmed that DLIR-GSI produces diagnostic quality images, even for extremely clinically challenging cases.

Substantial Equivalence

The changes associated with Deep Learning Image Reconstruction for Gemstone Spectral Imaging do not change the Intended 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 for Gemstone Spectral Imaging 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 Deep Learning Image Reconstruction for Gemstone Spectral Imaging 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.

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 for Gemstone Spectral Imaging is substantially equivalent to the predicate device and hence is safe and effective for its intended use.