Dear Lee Bush:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

[Signature]

Thalia Mills, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure
Indications for Use

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)

- [x] 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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Food and Drug Administration
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."
GE Healthcare
510(k) Premarket Notification Submission
Deep Learning Image Reconstruction

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS K183202

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 16, 2018

Submitter: GE Medical Systems, LLC
3000 North Grandview Blvd
Waukesha, WI 53188

Primary Contact: Lee Bush
Regulatory Affairs Manager
Phone 262-309-9429
Email: Lee.Bush@ge.com

Secondary Contacts: John Jaeckle
Chief Regulatory Affairs Engineer
GE Healthcare
Tel: 262-424-9547
Email: john.jaeckle@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

Primary Predicate Device Information

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

Secondary Predicate Device Information

Device Name: Revolution CT
Manufacturer: GE Medical System SCS (d.b.a GE Healthcare)
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 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 family of systems (K163213, K133705). 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.

As compared to the primary predicate device, the intended use of Deep Learning Image Reconstruction 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 taken at different angles and planes, including Axial, Helical (Volumetric), and Cardiac acquisitions for all ages.

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 GE Deep Learning Image Reconstruction option is substantially equivalent to existing reconstruction options including the primary predicate device, ASiR-V reconstruction option. Because both reconstruction options (Deep Learning Image Reconstruction and ASiR-V) are implemented on the secondary predicate, Revolution CT family (K163213, K133705), they utilize the same hardware and software platform technology on which substantial equivalency is
demonstrated. The table below summarizes the substantive feature/technological differences between the predicate device and the proposed device:

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Technology</td>
<td>Extensive system statistical model</td>
<td>Utilizes a dedicated Deep Neural Network (DNN) which is trained on the CT Scanner and designed specifically to generate high quality CT images</td>
</tr>
<tr>
<td>System statistics - Noise modeling of the data collection imaging chain (photon noise and electronic noise)</td>
<td>Characterization of the photon statistics as it propagates through the preprocessing and calibration imaging chain</td>
<td>Same</td>
</tr>
<tr>
<td>System statistics – Noise characteristics of the reconstructed images</td>
<td>The characterization of the scanned object using information obtained from extensive phantom and clinical data</td>
<td>Utilizes a trained Deep Neural Network (DNN) which models the scanned object using information obtained from extensive phantom and clinical data</td>
</tr>
<tr>
<td>Clinical Workflow</td>
<td>Select recon type and strength (percentage)</td>
<td>Select recon type and strength (High, Medium, Low)</td>
</tr>
</tbody>
</table>

Deep Learning Image Reconstruction does not introduce any new 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 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 bench testing performed, 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:

- Risk Analysis
- Required Reviews
- Design Reviews
Software Development Lifecycle
• Testing on unit level (Module verification)
• Integration testing (System verification)
• Performance testing (Verification)
• Safety testing (Verification)
• Simulated use testing (Validation)

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 ASIR-V.

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 CT and then applies the Deep Learning Image Reconstruction or ASiR-V reconstruction (hence the dose (CTDVol) 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
▪ 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)
▪ Low Contrast Detectability/resolution (statistical)
▪ 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

Clinical Testing
The reader study used a total of 60 retrospectively collected clinical cases. The raw data from each of these cases was reconstructed with both ASiR-V and Deep Learning Image Reconstruction.
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 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. Three readers read the cases primarily covering body and extremity anatomy, three different readers read the cases primarily covering head/neck anatomy, and three different readers read the cases primarily covering cardiac/vascular.

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.

A final evaluation of low contrast and small lesions in the abdominal and pelvis region by a board-certified radiologist confirmed that the images produced are of diagnostic quality.

Substantial Equivalence

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

Deep Learning Image Reconstruction was developed under GE Healthcare’s quality system. Design verification, along with bench testing and the clinical reader study demonstrate that 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 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 testing, the additional engineering bench testing, and the clinical reader study, 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.