GE Medical Systems SCS
% Kristine Schraufnagel
Senior Regulatory Affairs Manager
GE Medical Systems, LLC
3000 North Grandview Blvd.
WAUKESHA WI 53188

April 24, 2018

Re: K180225
Trade/Device Name: GSI Viewer with GSI Fat Option
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: January 26, 2018
Received: January 29, 2018

Dear Kristine Schraufnagel:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Michael D. O'Hara For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K180225

Device Name
GSI Viewer with GSI Fat Option

Indications for Use *(Describe)*
The GSI Viewer accepts images from a CT System that can acquire CT images using different kV levels of the same anatomical region of a patient in a single rotation from a single source. The differences in the energy dependence of the attenuation coefficient of the different materials provide information about the chemical composition of body materials. This approach enables images to be generated at energies selected from the available spectrum to visualize and analyze information about anatomical and pathological structures.
GSI provides information of the chemical composition of renal calculi by calculation and graphical display of the spectrum of effective atomic number. GSI Kidney stone characterization provides additional information to aid in the characterization of uric acid versus non-uric acid stones. It is intended to be used on non-contrast studies as an adjunct to current standard methods for evaluating stone etiology and composition.

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.

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510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	April 12, 2018
Submitter:	GE Medical Systems SCS 283, rue de la Minière 78530 Buc, France
Primary Contact Person:	Peter Uhlir Regulatory Affairs Leader Tel: 00 36 1 4793318 Fax: (262) 548 2317
Secondary Contact Person:	Kristine Schraufnagel Senior Regulatory Affairs Manager Tel: (262) 269-4273 Fax: (262) 548 2317
Device Trade Name:	GSI Viewer with GSI Fat Option
Common/Usual Name:	GSI Viewer with GSI Fat Option
Regulation Number: Classification Name: Classification Panel: Regulatory Class: Product Code:	21CFR 892.1750 Computed Tomography X-ray System Radiology Class II JAK
Predicate Device: Regulation Number: Classification Name: Classification Panel: Regulatory Class: Product Code:	K121827 – GSI Viewer with VUE Option 21CFR 892.1750 Computed Tomography X-ray System Radiology Class II JAK
Device Description / Intended Use:	The unmodified device GSI Viewer with VUE option (K121827) offers the Gemstone Spectral Imaging (GSI) capability that uses rapid kV switching to acquire the dual energy samples almost simultaneously. This enables generation of material density data that can be used for

	the separation of materials and derivation of monochromatic spectral images using a projection based reconstruction algorithm. GSI Viewer is a post processing visualization tool that allows users to view and process spectral images acquired by the GSI scan modes. It allows for the review of monochromatic energy images at user selectable energy levels, detailed analysis using material decomposed images (such as water-iodine, water calcium, etc.). and complementary information using the Effective-Z images by providing an estimate of the protons' effective atomic number in a voxel. With VUE option, it also produces a material suppressed image at a given monochromatic energy in the conventional CT Hounsfield Units. The modification being introduced is the Fat option that produces an approximation of a Fat percentage in the liver. This modification is based on the existing capability of the predicate device that generates material separated images in the Material Density (MD) space and VUE algorithm which is based upon Multi-Material Decomposition (MMD) a technique that allows for material separation and is the subject of this pre-market notification.
Indications for Use:	The GSI Viewer accepts images from a CT System that can acquire CT images using different kV levels of the same anatomical region of a patient in a single rotation from a single source. The differences in the energy dependence of the attenuation coefficient of the different materials provide information about the chemical composition of body materials. This approach enables images to be generated at energies selected from the available spectrum to visualize and analyze information about anatomical and pathological structures. GSI provides information of the chemical composition of renal calculi by calculation and graphical display of the spectrum of effective atomic number. GSI Kidney stone characterization provides additional information to aid in the characterization of uric acid versus non-uric acid stones. It is intended to be used on non-contrast studies as an adjunct to current standard methods for evaluating stone etiology and composition. The Indications for Use are identical to that of the predicate device.
Technology:	The GSI Viewer with GSI Fat Option software employs the same fundamental scientific technology as its predicate device. The GSI Viewer with GSI Fat Option relies on the predicate device's ability to generate material separated images in the material density (MD) space. Additionally, while the predicate device provides the ability to create fat as one of the material decomposed basis pairs (typically with iodine or calcium as the other basis) in units of

	voluminal mass (mg/ml or µg/ml), the GSI Viewer with GSI Fat Option adds the ability to provide a liver fat fraction.
Determination of Substantial Equivalence:	Summary of Non-Clinical Tests: The GSI Viewer with GSI Fat Option software complies with NEMA PS 3.1 - 3.20 (2016) Digital Imaging and Communications in Medicine (DICOM) Set (Radiology) standard. The GSI Viewer with GSI Fat Option software employs the same fundamental scientific technology as its predicate device, GSI Viewer with VUE Option. This modification is based on the existing capability of the predicate device that generates material separated images in the Material Density (MD) space and VUE algorithm which is based upon Multi-Material Decomposition (MMD) a technique that allows for material separation and is the subject of this pre-market notification. The following quality assurance measures were applied to the development of the system: ▪ Risk Analysis ▪ Requirements Reviews ▪ Design Reviews ▪ Integration testing (System verification) ▪ Performance testing (Bench testing, validation) ▪ Safety testing (Verification) The substantial equivalence determination is based on the software documentation for a MODERATE level of concern device. The substantial equivalence is established with performance testing involving: ▪ testing of accuracy based on different levels of fat using anthropomorphic and non-anthropomorphic (cylindrical with varying diameter) phantoms, ▪ testing confounding variable of iodinated contrast agent from clinical acquisition using comparison between contrasted and non-contrasted phases, ▪ testing confounding variable of hepatic iron based on different levels of fat and iron concentration using non-anthropomorphic phantom with accuracy comparison to MR.
Conclusion:	GE Healthcare considers the GSI Viewer with GSI Fat Option software application to be as safe, as effective, and performance is substantially equivalent to the predicate device.