March 9, 2023

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

Re: K223514
Trade/Device Name: Spectral Bone Marrow
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK, QIH
Dated: February 21, 2023
Received: February 22, 2023

Dear Katelyn 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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Imaging Devices
and Electronic Products
OHT8: Office of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223514

Device Name
Spectral Bone Marrow

Indications for Use *(Describe)*
Spectral Bone Marrow is an automated image processing software application, utilizing deep learning technology for bone segmentation, to facilitate optimized visualization of bone marrow in spectral body and extremity CT images. Spectral Bone Marrow's output can be used during the review of traumatic and non-traumatic bone pathologies.

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 OF SAFETY AND EFFECTIVNESS

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 22, 2022

Submitter: GE Medical Systems, LLC
3000 N. Grandview Blvd.
Waukesha, Wisconsin 53188

Primary Contact: Katelyn Rowley
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Device Trade Name: Spectral Bone Marrow

Device Classification Class II

Regulation Number/ Product Code: 21 CFR 892.1750 Computed tomography x-ray system / JAK
21 CFR 892.2050 Automated Radiological Image Processing Software / QIH

Predicate Device Information

Device Name: GSI Viewer with VUE Option

Manufacturer: GE Medical Systems, LLC

510(k) Number: K121827 cleared on September 13, 2012

Regulation Number/ Product Code: 21 CFR 892.1750 Computed tomography x-ray system / JAK

Device Description

Spectral Bone Marrow is a deep-learning based software analysis package designed for the visualization of bone marrow based on GE HealthCare's spectral CT acquisitions data. Spectral Bone Marrow assists clinicians by providing an automatically generated fused material density image of the segmented bone region over a base monochromatic image optimized for the visualization of bone

marrow during the review of traumatic or non-traumatic bone pathologies. The software creates a fully automated post processing workflow for creating these images and improving reader efficiency.

The Spectral Bone Marrow application involves generating a bone mask with a deep learning bone segmentation algorithm and uses this segmented region to define bone regions of water minus hydroxyapatite (Water(HAP)) material density images, which are subsequently colored. The application outputs the colored Water(HAP) material density images overlayed on monochromatic CT images or Virtual Unenhanced (VUE) images.

Additionally, the Spectral Bone Marrow application has the optional ability to automatically set the window width and window level of the color overlay images to provide for optimal visualization of bone marrow. The software provides multiplanar export of the fused images. Spectral Bone Marrow is hosted on GE's Edison Health Link (EHL) computational platform.

Indications for Use

Spectral Bone Marrow is an automated image processing software application, utilizing deep learning technology for bone segmentation, to facilitate optimized visualization of bone marrow in spectral body and extremity CT images. Spectral Bone Marrow's output can be used during the review of traumatic and non-traumatic bone pathologies.

Comparisons

The Spectral Bone Marrow software is substantially equivalent to the predicate device GSI Viewer with VUE Option (K121827). The fundamental technology, i.e generating the material density (MD) images, monochromatic images and overlaying the MD images over base images, remains unchanged from the predicate. The table below summarizes the substantive feature/technological differences between the predicate device and the proposed device. The changes described below do not change the fundamental technology and do not raise any issues of safety and effectiveness.

Specification/ Attribute	**GSI Viewer with VUE Option (Predicate Device, K121827)**	**Spectral Bone Marrow (Proposed Device)**
Bone Segmentation Technology	Manual segmentation	**Deep learning based segmentation**
Clinical Workflow	Manual	**Automated** - In the predicate device, the user has to manually segment the bone region, generate the MD images and fuse it/overlay them onto the monochromatic base images, and then export the output images as DICOM secondary captures and send them to desired DICOM destinations. In the subject device, a fully automated workflow generates the desired images (colored MD images of the segmented bone region overlaid on the monochromatic base or Virtual Unenhanced images) as secondary capture DICOM objects and networks them to the preconfigured DICOM destinations (e.g. PACS) for the user to review. This change in the subject device greatly improves the overall efficiency of the review workflow.
Deployment Environment	CT Console, AW Workstation (K110834), AW Server (K081985)	CT Console, **Edison Health Link (EHL)**
Algorithm Input	Dual energy DICOM images	Same
Algorithm Output	Dual energy images, including monochromatic, Virtual Unenhanced, and material density images and has the ability to output fused colored material density (MD) images (e.g Water (HAP)) of a segmented bone region overlaid on a monochromatic image as secondary capture DICOM series.	Fused image of colored material density (MD) images (e.g water (HAP)) of the segmented bone region overlaid onto the base monochromatic spectral CT images or **Virtual Unenhanced images**, as secondary capture DICOM series.

Determination of Substantial Equivalence

Summary of Non-Clinical Testing

Spectral Bone Marrow has successfully completed the design control testing per our quality system. No additional hazards were identified, and no unexpected test results were observed. Spectral Bone Marrow was designed under GE HealthCare's QMS per the Quality System Regulations of 21CFR 820 and ISO 13485.

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, Spectral Bone Marrow, is substantially equivalent to the predicate device.

The substantial equivalence is also based on the software documentation for a "Moderate" level of concern.

The non-clinical testing also included engineering bench testing that was carried out to verify the Spectral Bone Marrow's bone segmentation algorithm ability to accurately segment bone using a database of 146 retrospective Spectral CT series across a variety of GEHC Spectral Imaging CT Scanners. This database of exams is representative of the clinical scenarios where Spectral Bone Marrow is intended to be used. The ground truth for this dataset was generated by three US board certified radiologists, which was used to evaluate the Spectral Bone Marrow's bone segmentation. The result of the engineering bench testing showed that the algorithm is capable of accurately segment bones and is safe and effective for its intended use.

Clinical Testing

A representative set of clinical sample images was assessed by three board certified radiologists with expertise in both the evaluation of bone marrow and dual energy imaging review. The assessment used retrospectively collected clinical cases that were processed using the Spectral Bone Marrow software. Each image generated from the subject device were read by each board certified radiologist who

provided an assessment of image quality related to diagnostic use according to a Likert scale. Additionally, the readers were asked to rate their efficiency when using the algorithm compared to using without.

The result of this assessment validated that the Spectral Bone Marrow software provides additional diagnostic value for the evaluation of bone marrow and increased overall reader efficiency.

Substantial Equivalence

The changes associated with Spectral Bone Marrow do not change the Intended Use from the predicate and represent equivalent technology.

Spectral Bone Marrow was developed under GE HealthCare's quality system. Design verification, along with bench and clinical testing provided in this submission demonstrates that Spectral Bone Marrow 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 unexpected results, or adverse effects stemming from the changes to the predicate.

GE HealthCare believes that Spectral Bone Marrow is substantially equivalent to the predicate device and hence is safe and effective for its intended use.