U.S. FOOD & DRUG ADMINISTRATION

GE Medical Systems SCS
% Ms. Elizabeth Mathew
Senior Regulatory Affairs Manager
283 rue de la Miniere
Buc, 78530
FRANCE

April 8, 2019

Re: K183204
Trade/Device Name: Bone VCAR (BVCAR)
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK, LLZ
Dated: March 18, 2019
Received: March 19, 2019

Dear Elizabeth Mathew:

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,

For

Thalia T. Mills, 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)*
K183204

Device Name

Bone VCAR

Indications for Use *(Describe)*

Bone VCAR is a post processing application for use in the analysis of CT images. The software is intended to support clinicians in the review of images that include the spine by providing tools to label the spine and optimize the display of anatomy within the CT image.

Bone VCAR is designed to support the clinician in visualization of the spine, by providing initial identification of vertebrae to assist in report dictation.

The software also assists the user by providing optimized display settings for easier identification of anatomy to facilitate fast image review and reporting of findings. Bone VCAR may be used for multiple care areas and is not specific to any disease state. It can be utilized during the review of various types of exams including trauma, oncology, and routine body.

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.

510(k) Summary K183204

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

Date:	April 8, 2019
Submitter:	GE Medical Systems SCS Establishment Registration Number - 9611343 283 rue de la Miniere 78530 Buc, France
Primary Contact Person:	Elizabeth Mathew Senior Regulatory Affairs Manager Phone: (262) 424-7774 Email: Elizabeth.Mathew@ge.com
Secondary Contact Person:	Helen Peng Regulatory Affairs Director GE Healthcare, (GE Medical Systems, LLC) 3000 N Grandview Blvd., Waukesha, WI - 53188 Phone: 262-424-8222 Email: Hong.Peng@ge.com

Proposed Device:

Device Name:	Bone VCAR
Common/Usual Name:	BVCAR
Primary Regulation number:	21 CFR 892.1750 Computed tomography x-ray system
Primary Product Code:	JAK
Secondary Product Code:	LLZ
Classification:	Class II

Predicate Device:	
Device Name:	Syngo.CT Bone Reading
510(k) number:	K123584 cleared on May 12, 2013
Regulation number/ Product Code:	21 CFR 892.1750 Computed tomography x-ray system / JAK
Classification:	Class II
Manufacturer:	Siemens Medical Solutions, USA

Device Description/ Technology:

Bone VCAR is a software analysis package utilizing a deep learning technique that assists in the analysis and visualization of CT data. It is intended to provide clinicians with an optimized display and quick access to tools that improve the reading experience and efficiency for anatomy. Bone VCAR is a post processing application option for the Advantage Workstation (AW) platform, CT Scanner, Cloud or PACS stations which can be used in the analysis of CT images.

Bone VCAR is designed to support the clinician in easy visualization of spine and to provide identification of those structures to assist in report dictation. This post processing solution combines the following tools and functionality:

• Multiplanar Reconstruction (MPR) displays of axial, sagittal, coronal, oblique, x-section and curved views which can be displayed in thin/thick, Average, Maximum Intensity Projection (MIP), Minimum intensity Projection (MinIP), Volume Rendering (VR) modes

• Display of anatomical labels automatically with editing capability of all labels such as the spine.

• Display of curved views automatically and editing capability of curved views through anatomical regions such as the spine for enhanced display options

• Access to all standard volume viewer tools for measuring distances, areas, Hounsfield unit values and annotating within the images

• Synchronization of views when multiple series are loaded with spine labeling for all series loaded.

The software will assist the user by providing optimized display settings to enable fast review of the images along with easy identification of anatomy to ease reporting of findings. Bone VCAR may be used for multiple care areas and is not specific to any disease state. It can be utilized during the review of various types of exams including trauma, oncology, and routine body.

Bone VCAR is compatible with both single energy and Gemstone Spectral Imaging (GSI) acquisition methods.

The labeling tool can be activated and deactivated by the user at any time during the image review. Multiple volumes of data can be processed with the Bone VCAR tool at the same time. Volumes can be from the same or different exams. All labels can be moved, edited, hidden or deleted.

The dedicated display layout should assist in easy review of the anatomy. Users have the flexibility for using all or a subset of the features within this application as they find suitable.

Intended Use:

Bone VCAR is a non-invasive image analysis software package which may be used in conjunction with CT images to aid in the assessment and reporting efficiency of images that include the spine.

Indication for Use:

Bone VCAR is a post processing application for use in the analysis of CT images. The software is intended to support clinicians in the review of images that include the spine by providing tools to label the spine and optimize the display of anatomy within the CT image.

Bone VCAR is designed to support the clinician in visualization of the spine, by providing initial identification of vertebrae to assist in report dictation.

The software also assists the user by providing optimized display settings for easier identification of anatomy to facilitate fast image review and reporting of findings. Bone VCAR may be used for multiple care areas and is not specific to any disease state. It can be utilized during the review of various types of exams including trauma, oncology, and routine body.

Technological Characteristic:

The goal of the Bone VCAR software algorithm is to extract from a CT scan the positions and labels of the patient vertebrae in the image. The algorithm takes as input a CT scan acquisition and is compatible with a wide range of acquisitions for dedicated spine work, trauma, oncology and routine exam. Bone VCAR automated vertebra detection algorithm returns the list of detected vertebrae position in 3D coordinates and associated labels.

Comparison:

The table below summarizes the feature/technological comparison between the predicate device and the proposed device:

Specification	Syngo CT Bone Reading (K123584)	Proposed Device: Bone VCAR
Spine Labeling Tool	Automated labeling with manual editing capability	Automated labeling with manual editing capability
Display of curved spine structures	Yes	Yes
Measurement Tool	geometric measurement tools (distance line, polyline, marker, arrow, angle), HU measurement tools (Pixel lens, ROI circle, ROI polygonal, ROI freehand, VOl sphere)	Access to all standard Volume Viewer tools for measuring distances, areas, Hounsfield unit values and annotating within the images
Image Display formats	Multiplanar reconstruction (MPR) thin/thick, maximum intensity projection (MIP) thin/thick, inverted MIP thin/thick, volume rendering technique (VRT)	Multiplanar Reconstruction (MPR) displays of axial, sagittal, coronal, oblique, x-section and curved views which can be displayed in thin/thick, Average, Maximum Intensity Projection (MIP), Minimum intensity Projection (MinIP), Volume Rendering (VR) modes.

Determination of Substantial Equivalence:

Engineering has validated Bone VCAR algorithm's capability of using deep learning technique to automatically label spine using a dataset of CT exams. This database of exams is considered as a representative of the clinical scenarios where Bone VCAR is intended to be used, with consideration of acquisition parameters, image quality, pathologies and anatomy variations. The result of the algorithm validation provided a success rate greater than 90% for the capability of automatically labeling the spine.

A representative set of clinical sample images was assessed by three board certified radiologists using 5-point Likert scale. The assessment demonstrated that the capability of automatic labeling of spine by Bone VCAR is faster than

manually labeling and it also increases reading and reporting efficiency whilst providing accurate identification of vertebra.

Bone VCAR has successfully completed the required design control testing per GE's quality system. Bone VCAR was designed and will be manufactured under the Quality System Regulations of 21CFR 820 and ISO 13485. The following quality assurance measures have been applied to the development of the device:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Performance testing (Verification, Validation)
- Safety testing (Verification)

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

Conclusion:

GE Healthcare considers Bone VCAR to be as safe, as effective, and performance is substantially equivalent to the predicate device.