510(k) Summary K183204

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

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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.