DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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