July 13, 2023

GE Medical Systems SCS
℅ Yonghui Han
Senior Regulatory Affairs Leader
283, rue de la Miniere
BUC, 78530
FRANCE

Re: K223424
Trade/Device Name: Spine Auto Views
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK, QIH
Dated: June 9, 2023
Received: June 12, 2023

Dear Yonghui Han:

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 Radiological 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)*
K223424

Device Name
Spine Auto Views

Indications for Use *(Describe)*
Spine Auto Views is a non-invasive image analysis software package which may be used in conjunction with CT images to aid in the automatic generation of anatomically focused multi-planar reformats and automatically export results to pre-determined DICOM destinations.

Spine Auto Views assists clinicians by providing anatomically focused reformats of the spine, with the ability to apply anatomical labels of the vertebral bodies and intervertebral disc spaces.

Spine Auto Views may be used for multiple care areas and is not specific to any disease state. It can be utilized for 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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## 510(k) Summary

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

| | |
|---|---|
| Date: | July 7, 2023 |
| Submitter: | GE Medical Systems SCS<br>Establishment Registration Number - 9611343<br>283 rue de la Miniere<br>78530 Buc, France |
| Primary Contact Person: | Yonghui Han<br>Senior Regulatory Affairs Leader<br>GE HealthCare<br>(+1) (262)225-1914<br>Yonghui.Han@ge.com |
| Secondary Contact Person: | Elizabeth Mathew<br>Senior Regulatory Affairs Manager<br>GE HealthCare<br>Tel: (+1) (262)424-7774<br>Email: Elizabeth.Mathew@ge.com |
| Device Trade Name: | Spine Auto Views |
| Common/Usual Name: | Spine Auto Views |
| Primary Regulation Number:<br>Primary Product Code:<br>Secondary Product Code:<br>Classification: | Computed Tomography X-Ray System (21 CFR 892.1750)<br>JAK<br>QIH<br>Class II |

| **Predicate Device** | |
|---|---|
| Device name: | Bone VCAR |
| Manufacturer: | GE Medical Systems SCS |
| 510(k) number: | K183204 |
| Regulation Number: | 21 CFR 892.1750 Computed tomography X-Ray System |
| Primary Product Code: | JAK |
| Secondary Product Code: | LLZ |
| Classification: | Class II |

**Device Description:**

Spine Auto Views is a software analysis package designed to generate batch reformats and apply labels to the spine. It is intended to streamline the process of generating clinically relevant batch reformat outputs that are requested for many CT exam types.

Spine Auto Views can generate, automatically, patient specific, anatomically focused spine reformats. Spine Auto Views brings a state-of-the-art deep learning algorithm that generates oblique axial reformats, appropriately angled through each disc space without the need for a user interface and human interaction. 3D curved coronal and curved sagittal views of the spine as well as traditional reformat planes can all be generated with Spine Auto Views, no manual interaction required. Vertebral bodies and disc spaces can be labeled, and all series networked to desired DICOM destination(s), ready to read. The automated reformats may help in providing a consistent output of anatomically orientated images, labeled, and presented to the interpreting physician ready to read.

**Intended Use:**

Spine Auto Views is a non-invasive image analysis software package which may be used in conjunction with CT images to aid in the automatic generation of anatomically focused multi-planar reformats.

**Indication for Use:**

Spine Auto Views is a non-invasive image analysis software package which may be used in conjunction with CT images to aid in the automatic generation of anatomically focused multi-planar reformats and automatically export results to pre-determined DICOM destinations.

Spine Auto Views assists clinicians by providing anatomically focused reformats of the spine, with the ability to apply anatomical labels of the vertebral bodies and intervertebral disc spaces.

Spine Auto Views may be used for multiple care areas and is not specific to any disease state. It can be utilized for the review of various types of exams including trauma, oncology, and routine body.

**Technology:**

The proposed device Spine Auto Views employs the same fundamental scientific technology as its predicate device.

**Comparison:**

The table below summarizes the key feature/technological differences and similarities between the predicate device and the proposed device:

Table 5.1: Comparison

| **Specification** | **Predicate Device: Bone VCAR (K183204)** | **Subject Device: Spine Auto Views** | **Comparison** |
|---|---|---|---|
| **CT Spine Labeling algorithm**<br><br>(Vertebrae Detection and Vertebrae Labels) | Yes | Yes | **Identical** |

| Specification | Predicate Device:<br>Bone VCAR (K183204) | Subject Device:<br>Spine Auto Views | Comparison |
|---|---|---|---|
| **Disc Detection algorithm**<br><br>(Disc Position, Disc Orientation & Disc Labels) | Not available | Yes | **Substantially Equivalent.**<br><br>Spine Auto Views introduces a new deep learning Disc detection algorithm which can detect discs positions, planes/orientations and generate disc labels. |
| **Image Display Formats** | Traditional reformat orientations (axial, coronal, sagittal) | Traditional reformat orientations (axial, coronal, sagittal) | **Identical** |
| | Curved coronal and curved sagittal views of the spine as well as oblique axial views perpendicular to the 3D curved trace. | Curved coronal and curved sagittal views of the spine as well as oblique axial views through the intervertebral spaces. | **Substantially Equivalent**<br><br>Both the subject device and predicate device can output curved coronal and curved sagittal views and oblique axial view. However, the methodology in which these reformat series are generated are different between the subject device and predicate device.<br><br>For the curved reformats, Bone VCAR uses the centerline traced through the vertebrae centers; Spine Auto Views use the centerline traced through the posterior |

| Specification | Predicate Device:<br>Bone VCAR (K183204) | Subject Device:<br>Spine Auto Views | Comparison |
|---|---|---|---|
| | | | edge of the disc centers.<br><br>For oblique axial views generation, the oblique axial of Bone VCAR is perpendicular to its centerline. Spine Auto Views uses the computed position and orientation of the discs. |
| **Field of View** | Bone VCAR uses input volume field of view and manually adjusted by the user. | Spine Auto Views uses input volume field of view and additionally has an option to automatically set the field of view to focus on the spine | **Substantially Equivalent**<br><br>The subject device has two configurations: input series field of view, or automated field of view focused on the spine. |
| **Export** | Manual | Automated | **Substantially Equivalent**<br><br>In the subject device, all generated series can be automatically exported to DICOM destinations, such as PACS, ready for review and interpretation. |
| **Measurement Tool** | Access to all standard Volume Viewer tools for measuring distances, areas, Hounsfield unit values and annotating within the images | Not available | Subject device doesn't have a user interface and doesn't include measurement tools. Subject device provides DICOM reformat images for export. |

**Determination of Substantial Equivalence:**

Summary of Non-Clinical, Design Control Testing

Spine Auto Views has successfully completed the design control testing per GE's quality system. It was designed and will be manufactured under the Quality System Regulations of 21CFR 820 and ISO 13485. No additional hazards were identified, and no unexpected test results were observed. The proposed device complies with NEMA PS 3.1 - 3.20 (2016) Digital Imaging and Communications in Medicine (DICOM) Set (Radiology) standard.

The following quality assurance measures were applied to the development of the device:

- Requirements Definition
- Risk Analysis
- Technical Design Reviews
- Formal Design Reviews
- Software Development Lifecycle
- Performance testing (Verification, Validation)
- Safety Testing (Verification)

The proposed Spine Auto Views has been successfully verified on the EHL platform. All the testing and results did not raise new or different questions of safety and effectiveness other than those already associated with predicate device. Software documentation is for a MODERATE level of concern.

In addition, Engineering has validated Spine Auto Views algorithm capability to automatically detect the position and orientation of intervertebral discs using a database of retrospective CT exams. This database of exams is representative of the clinical scenarios where Spine Auto Views is intended to be used, with consideration of acquisition parameters and patient characteristics. The result of the algorithm validation showed that the algorithm successfully passed the defined acceptance criteria.

Summary of Clinical Testing

A reader study evaluation was performed with a sample of clinical CT images which were processed with the Spine Auto Views software. The purpose of this study was to assess the acceptance of spine automated reformats generated in the oblique axial, curved coronal and curved sagittal planes as these orientations traditionally require users to manually generate each of them. The reader evaluation concluded that Spine Auto Views oblique axial reformats generates user acceptable results greater than 95% of the time for all readers. Additionally, the batch reformats of curved coronal and curved sagittal views were also assessed by the readers by comparing the automatically generated curved batch reformats with the corresponding standard coronal and standard sagittal views.

**Conclusion:**

Spine Auto Views has the same intended use as its predicate device but differs in technological characteristics. Specifically Spine Auto Views automatically generates spine reformat DICOM

images by detecting the vertebras and discs in the scan while the predicate requires more manual interactions.

GE HealthCare's quality system's design, verification, and risk management processes did not identify any new questions of safety or effectiveness, hazards, unexpected results, or adverse effects stemming from the changes to the predicate.

Based on development under GE HealthCare's quality system, successful design verification, software documentation for a "Moderate" level of concern, along with the engineering bench testing and reader study, GE HealthCare determines that the proposed device is as safe and effective as its predicate device.