Siemens Medical Solutions USA, Inc.
% M. Alaine Medio
Regulatory Affairs Professional
810 Innovation Drive
KNOXVILLE TN 37932

March 16, 2020

Re: K193267
Trade/Device Name: Al-Rad Companion (Musculoskeletal)
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: February 20, 2020
Received: February 21, 2020

Dear M. Alaine Medio:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*

K193267

Device Name
AI-Rad Companion (Musculoskeletal)

Indications for Use *(Describe)*

AI-Rad Companion (Musculoskeletal) is an image processing software that provides quantitative and qualitative analysis from previously acquired Computed Tomography DICOM images to support radiologists and physicians from emergency medicine, specialty care, urgent care, and general practice in the evaluation and assessment of musculoskeletal disease. It provides the following functionality:

- Segmentation of vertebras
- Labelling of vertebras
- Measurements of heights in each vertebra and indication if they are critically different
- Measurement of mean Hounsfield value in volume of interest within vertebra.

Only DICOM images of adult patients are considered to be valid input

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
## FOR AI-RAD COMPANION (MUSCULOSKELETAL)
## K193267

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

Identification of the Submitter

| | |
|---|---|
| Manufacturer: | Siemens Healthcare GmbH<br>Siemensstr. 1<br>D-91301 Forchheim, Germany<br>**Establishment Registration Number**<br>3004977335 |
| Importer / Distributor: | Siemens Medical Solutions USA, Inc.<br>40 Liberty Boulevard<br>Malvern, PA 19355<br>**Establishment Registration Number**<br>2240869 |
| Submitter: | M. Alaine Medio, RAC<br>Regulatory Affairs<br>Siemens Medical Solutions USA, Inc.<br>Molecular Imaging<br>810 Innovation Drive<br>Knoxville, TN 37932 |
| Alternative Contact: | Tabitha Estes<br>Regulatory Affairs |
| Telephone Number: | (865)206-0337 |
| Fax Number: | (865)218-3019 |
| Date of Submission: | November 25, 2019 |

Identification of the product

| | |
|---|---|
| Device Proprietary Name: | AI-Rad Companion (Musculoskeletal) |
| Common Name: | AI-Rad Companion (Musculoskeletal) |
| Classification Name: | Computed Tomography X-ray System |
| Regulation: | 21 CFR 892.1750 |
| Product Code: | JAK |
| Classification Panel: | Radiology |
| Device Class: | Class II |

Marketed Devices to which Equivalence is claimed

**Predicate Device:**

| | |
|---|---|
| Device Proprietary Name: | syngo.CT Bone Reading |
| Manufacturer: | Siemens Healthcare GmbH |
| Classification Name: | Computed Tomography X-ray System |
| Regulation: | 21 CFR 892.1750 |
| Product Code: | JAK |
| Classification Panel: | Radiology |
| Device Class: | Class II |
| 510(k) Number: | K123584 cleared March 12, 2013 |

**Reference Device:**

| | |
|---|---|
| Device Proprietary Name: | AI-Rad Companion (Cardiovascular) |
| Manufacturer: | Siemens Healthcare GmbH |
| Classification Name: | Computed Tomography X-ray System |
| Regulation: | 21 CFR 892.1750 |
| Product Code: | JAK |
| Subsequent Product Code | LLZ |
| Classification Panel: | Radiology |
| Device Class: | Class II |
| 510(k) Number: | K183268 cleared October 09, 2019 |

**Device Description**

AI-Rad Companion (Musculoskeletal) is software-only image post-processing application that uses deep learning algorithms to post-process CT data of the thorax. AI-Rad Companion (Musculoskeletal) supports workflows for visualization and various measurements of musculoskeletal disease, including:

- Segmentation of vertebras
- Labelling of vertebras
- Measurements of heights in each vertebra and indication if they are critically different
- Measurement of mean Hounsfield value in volume of interest within vertebra

As an update to the previously cleared predicate device, the following modifications have been made:

1) Modified Indication for Use Statement
2) Support of software AI-Rad Companion VA10
    a. Detection of vertebras (identical)
    b. Labelling of Vertebras (identical)
    c. Segmentation, Size/HU measurement (**modified**)
    d. Vertebra categories (**modified**)
3) Subject device claims list

AI-Rad Companion (Musculoskeletal) uses the same deep learning technology as in the previously cleared reference device Siemens AI-Rad Companion (Cardiovascular) (K183268). More precisely, a 3D Deep Image-to-Image network is used for organ segmentation. The main structure of the network is designed following a symmetric way as a convolutional encoder-decoder. All blocks of the network consist of 3D convolutional and bilinear upscaling layers.

**Indications for Use**

AI-Rad Companion (Musculoskeletal) is an image processing software that provides quantitative and qualitative analysis from previously acquired Computed Tomography DICOM images to support radiologists and physicians from emergency medicine, specialty care, urgent care, and general practice in the evaluation and assessment of musculoskeletal disease.

It provides the following functionality:

- Segmentation of vertebras
- Labelling of vertebras
- Measurements of heights in each vertebra and indication if they are critically different

- Measurement of mean Hounsfield value in volume of interest within vertebra.

Only DICOM images of adult patients are considered to be valid input.

| Subject Device | Predicate Device |
|---|---|
| **Siemens<br>AI-Rad Companion (Musculoskeletal)** | **Siemens<br>syngo.CT Bone Reading<br>(K123585)** |
| AI-Rad Companion (Musculoskeletal) is an image processing software that provides quantitative and qualitative analysis from previously acquired Computed Tomography DICOM images to support radiologists and physicians from emergency medicine, specialty care, urgent care, and general practice in the evaluation and assessment of musculoskeletal disease.<br><br>It provides the following functionality:<br>• Segmentation of vertebras<br>• Labelling of vertebras<br>• Measurements of heights in each vertebra and indication if they are critically different<br>• Measurement of mean Hounsfield value in volume of interest within vertebra<br><br>Only DICOM images of adult patients are considered to be valid input. | The syngo.CT Bone Reading is image analysis software for CT volume data sets which has. been continuously acquired with computed tomography (CT) imaging systems. The software combines following digital image processing and visualization tools:<br><br>• multiplanar reconstruction (MPR) thin/thick, maximum intensity projection (MIP) thin/thick, inverted MIP thin/thick, volume rendering technique (VRT)<br>• geometric measurement tools (distance line, polyline, marker, arrow, angle)<br>• HU measurement tools (Pixel lens, ROI circle, ROi polygonal, ROI freehand, VOl sphere)<br>• curved MPR visualization (unfolded ribs and spine views), crosssection MPRs<br>• tools for creation and editing of anatomical centerline paths<br>• tools for creation and editing of anatomical labels<br><br>The specific visualizations of spine and rib structures allow for easy manual identification and marking of pathologies such as bone lesions or fractures.<br><br>Reporting and documentation of results is facilitated by using of appropriate reporting tool, statistics and creation of ranges and snapshots |

The Indications for Use for the subject device provides the following modifications as compared to the predicate device:

1. New Subject Device Name: AI-Rad Companion (Musculoskeletal)
2. The general goal of the subject device is to evaluate vertebras. The fundamental functionality as listed is in the subject device's Indications for Use is similar to the predicate device's Indications for Use. Features like segmentation and labeling of vertebras are marked as "HU Measurement tools" and "Tools for creation and editing of anatomical labels" in the predicate device. Measurement of heights and HU refer to "geometric measurement tools" and "HU measurement tools" in the predicate device' Indications for Use.

The AI-Rad Companion (Musculoskeletal) Indication for Use Statement was revised to reflect subject device specific functionality and to improve clarity. This IFU statement operates within the scope of the intended use for this and the cleared primary predicate device.

**Comparison of Technological Characteristics with the Predicate Device**

In comparison to the predicate device, the subject device provides comparable outputs in terms of vertebrae visualization/segmentation and labeling. A tabular high-level comparison of the subject device and predicate device as well as the refence device is provided as Table 1 and Table 2 below.

*Table 1 Predicate Device Comparable Properties*

| Feature | Subject Device | Predicate Device | Comparison Results |
|---|---|---|---|
| | Siemens AI-Rad Companion (Musculoskeletal) | syngo.CT Bone Reading (K123584) | |
| Detection of vertebrae | Detection of Vertebras | Detection of Vertebras | Same |
| Labeling of vertebrae | Labelling of vertebras | Labelling of vertebras | Same |
| Segmentation of vertebrae | Deep-learning-based segmentation of vertebras | Model-based segmentation of vertebras | Equivalent *1) |
| Measurement of heights | Distance measurements based on segmentation results and comparison with neighboring measurements | Manual distance measurements in vertebra and visual comparison with neighboring vertebra(s) | Equivalent *2) |
| Measurement of Hounsfield (HU) value | HU measurements based on segmentation results | HU measurement in region of interest | Equivalent *3) |

Explanation to 1, 2, 3:

*1) Segmentation in predicate device is a model-based approach, in the subject device, however, a deep-learning algorithm has been included.

*2) The workflow in the predicate device requires manual height measurements, the user has to compare the measured heights applying the Genant criteria. In the subject device, the height measurements are automatically performed including the comparisons to the neighboring counterpart and the application of the Genant criteria.

*3) The Algorithm of the subject device uses the output of the segmentation step and fits a cylinder into each vertebra. Herein, the mean Hounsfield value is calculated.

*Table 2 Reference Device Comparable Properties*

| Feature | Subject Device | Reference Device | Comparison Result |
|---|---|---|---|
| | Siemens AI-Rad Companion (Musculoskeletal) | Siemens AI-Rad Companion (Cardiovascular) (K183268) | |
| Deep Learning Technology | Deep Image-to-image network for 3D segmentation of organs | Deep Image-to-image network for 3D segmentation of organs | Same |

AI-Rad Companion (Musculoskeletal) uses the same deep learning technology as the reference device AI-Rad Companion (Cardiovascular): a 3D Deep Image-to-Image network is used for organ segmentation. The main structure of the network is designed following a symmetric way as a convolutional encoder-decoder. All blocks of the network consist of 3D convolutional and bilinear upscaling layers.

## Performance Data

### Non-Clinical Performance Data Summary

The performance data demonstrates continued conformance with special controls for medical devices containing software. Non-clinical tests were conducted on the Subject Device AI-Rad Companion (Musculoskeletal) software version VA10 during product development. These tests are documented via Verification and Validation Traceability Analysis. For the subject device., Siemens used the same testing process with the same testing workflow as used to clear the predicate device. The result of all testing conducted was found acceptable to support the claim of substantial equivalence.

### Clinical Performance Data Summary

The performance of the AI-Rad Companion (Musculoskeletal) device has been validated in a retrospective performance study on chest CT data (N=140, data from multiple clinical sites across the United States and Europe). Ground truth annotations were established using manual vertebra height and density measurements performed by four radiologists (two readers per case plus a third reader for adjudications). Inter-reader-variability, i.e. the 95%-limits of agreement (LoA) of the measurements performed by the radiologists, was assessed. The ratio of vertebra height measurements generated by the subject device lying within the LoA around the ground truth was 95.1% for thin slices (≤1 mm slice thickness) and 87.5% for thicker slices (>1 mm slice thickness). Analogously the ratio of vertebra density measurements lying within the LoA was 98.8%. Performance was consistent for all critical subgroups, such as vendors or reconstruction parameters and patient age.

### Risk Analysis Summary

The Risk analysis was completed, and risk control implemented to mitigate identified hazards. The testing results support that all the software specifications have met the acceptance criteria. Testing for verification and validation for the device was found acceptable to support the claims of substantial equivalence.

### Voluntary Conformance Standards

AI-Rad Companion has been tested to meet the requirements of conformity to multiple industry standards. Non-clinical performance testing demonstrated that AI-Rad Companion complies with the following voluntary FDA recognized Consensus Standards listed in Table 3 below.

*Table 3 Voluntary Conformance Standards*

| Recognition Number | Product Area | Title of Standard | Publication Date | Standards Development Organization |
|---|---|---|---|---|
| 12-300 | Radiology | Digital Imaging and Communications in Medicine (DICOM) Set; PS 3.1 – 3.20 | 06/27/2016 | NEMA |
| 13-79 | Software | Medical Device Software –Software Life Cycle Processes;<br>IEC 62304 Edition 1.1 2015-06 | 06/26/2015 | IEC |
| 5-40 | Software/ Informatics | Medical devices – Application of risk management to medical devices;<br>14971 Second Edition 2007-03-01 | 08/20/2012 | ISO |

**Cybersecurity**
Siemens conforms to the cybersecurity requirements by implementing a process of preventing unauthorized access, modifications, misuse or denial of use, or the unauthorized use of information that is stored, accessed or transferred from a medical device to an external recipient. Provided in this submission is a cybersecurity statement that considers IEC 80001-1:2010. The responsibility for compliance with IEC 80001-1-2010 is the hospital.

**Summary**
AI-Rad Companion (Musculoskeletal) was tested and found to be safe and effective for intended users, uses and use environments through the design control verification and validation process and clinical data-based software validation. The Human Factor Usability Validation showed that Human factors are addressed in the system test according to the operator's manual and in clinical use tests with customer report and feedback form. Customer employees are adequately trained in the use of this equipment.

## General Safety and Effectiveness:

The device labeling contains instructions for use as well as necessary cautions and warnings to provide for safe and effective use of the device. Risk management is ensured via a system related Risk analysis, which is used to identify potential hazards. These potential hazards are controlled during development, verification and validation testing according to the Risk Management process. In order to minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

## Conclusions

AI-Rad Companion (Musculoskeletal) has the same intended use as the predicate device. The indications for use have been modified to include a more succinct summary of device specific performance, but is still within the scope of the intended use and regulatory classification of the predicate device. The fundamental technological characteristics, such as image visualization and image manipulation, are the same as the predicate device. The result of all testing conducted was found acceptable to support the claim of substantial equivalence.

The predicate device was cleared based on non-clinical supportive evidence. The results of those tests demonstrated that the predicate device was adequate for the intended use.

The comparison of technological characteristics, non-clinical performance data, and software validation demonstrates that the subject device is as safe and effective when compared to the predicate device that is currently marketed for the same intended use.

For the subject device, AI-Rad Companion (Musculoskeletal), Siemens used the same testing with the same workflows used to clear the predicate device to demonstrate safety and performance of the technical workflow. Clinical applicability was demonstrated via software-data based validations that were derived in the same intended environment as the predicate device. Since both devices were tested using the same methods, Siemens believes that the data generated from the AI-Rad Companion (Musculoskeletal) software testing supports a finding of substantial equivalence.