Medical Metrics, Inc.
Kirk Johnson
Director of Regulatory and Quality Affairs
2121 Sage Road
Suite 300
HOUSTON, TEXAS 77056

July 7, 2023

Re: K231668
Trade/Device Name: Spine CAMP™ (1.1)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: June 7, 2023
Received: June 7, 2023

Dear Kirk Johnson:

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,

Jessica Lamb

Jessica Lamb,
Assistant Director
Imaging Software 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.

Submission Number *(if known)*

K231668

Device Name

Spine CAMP™ (1.1)

Indications for Use *(Describe)*

Spine CAMP™ is a fully-automated software that analyzes X-ray images of the spine to produce reports that contain static and/or motion metrics. Spine CAMP™ can be used to obtain metrics from sagittal plane radiographs of the lumbar and/or cervical spine and it can be used to visualize intervertebral motion via an image registration method referred to as "stabilization." The radiographic metrics can be used to characterize and assess spinal health in accordance with established guidance. For example, common clinical uses include assessing spinal stability, alignment, degeneration, fusion, motion preservation, and implant performance. The metrics produced by Spine CAMP are intended to be used to support qualified and licensed professional healthcare practitioners in clinical decision making for skeletally mature patients of age 18 and above.

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.

medicalmetrics INC.
Insight from Imaging

Medical Metrics, Inc.
2121 Sage Road, Suite 300
Houston, Texas 77056

P 713-850-7500
F 713-850-7527
www.medicalmetrics.com

510(K) SUMMARY 510(K) #K231668

Submitter Information [21 CFR 807.929(a)(1)]	
Name	Medical Metrics, Inc.
Address	2121 Sage Road, Suite 300 Houston, Texas 77056
Phone number	+1 713 850-7500
Fax number	+1 713 850-7527
Email address	kjohnson@medicalmetrics.com
Establishment Registration Number	Pending 510(k) clearance and marketing of device
Name of contact person	Kirk Johnson
Date prepared	07/05/2023
Name of the device [21 CFR 807.92(a)(2)]	
Trade name	Spine CAMP™ (1.1)
Regulation name	Medical Image Management and Processing System
Review panel	Radiology
Regulation Number	892.2050
Product Code	QIH
Legally marketed device to which equivalence is claimed [21 CFR 807.92(a)(3)]	Spine CAMP™ v1.0 (K221632)
Device description [21 CFR 807.92(a)(4)]	Spine CAMP™ is a fully-automated image processing software device. It is designed to be used with X-ray images and is intended to aid medical professionals in the measurement and assessment of spinal parameters. Spine CAMP™ is capable of calculating distances, angles, linear displacements, angular displacements, and mathematical combinations of these metrics to characterize the morphology, alignment, and motion of the spine. These analysis results are presented in the form of reports, annotated images, and visualizations of intervertebral motion to support their interpretation.
Indications for use [21 CFR 807.92(a)(5)]	Spine CAMP™ is a fully-automated software that analyzes X-ray images of the spine to produce reports that contain static and/or motion metrics. Spine CAMP™ can be used to obtain metrics from sagittal plane radiographs of the lumbar and/or cervical spine and it can be used to visualize intervertebral motion via an image registration method referred to as “stabilization.” The radiographic metrics can be used to characterize and assess spinal health in accordance with established guidance. For example, common clinical uses include assessing spinal stability, alignment, degeneration, fusion, motion preservation, and implant performance. The metrics produced by Spine CAMP™ are intended to be used to support qualified and licensed professional healthcare practitioners in clinical decision-making for skeletally mature patients of age 18 and above.

Summary of the technological characteristics of the device compared to the predicate device [21 CFR 807.92(a)(6)]		
Feature	**Spine CAMP™ v1.1 (Subject Device)**	**Spine CAMP™ v1.0 (Predicate Device K221632)**
Classification Name	Automated Radiological Image Processing Software	Automated Radiological Image Processing Software
Product Code	QIH	QIH
Runs on Server	Yes	Yes
Image Input	DICOM	DICOM
Anatomical Area	Spine	Spine
Image Processing	Vertebral body detection; Vertebral body landmark specification; Vertebral body registration	Vertebral body detection; Vertebral body landmark specification; Vertebral body registration
Linear Measurements	Yes	Yes
Angular Measurements	Yes	Yes
2D Motion Analysis	Yes	Yes
Image Registration	Yes	Yes
Display of Image Alignment / Stabilization	Yes	Yes
Clinical Reporting	Yes	Yes
Human Intervention for Interpretation	Required	Required
Intended User	Trained professionals	Trained professionals

Comparison Summary

Spine CAMP™ v1.1 is designed to utilize the same analysis methodology as the predicate device, Spine CAMP™ v1.0 (K221632). The types of inputs and outputs are identical between the two devices. The devices are nearly identical in all respects. The primary differences are:

- Spine CAMP's primary component, the AI Engine, was updated by retraining its AI models with more imaging for improved generalization and performance. Improvements were also made to the AI Engine's logic to address potential failure modes.
- Spine CAMP™ v1.1 is able to identify the femoral heads in lateral lumbar X-rays in order to produce spinopelvic measurements.
- Configuration capabilities were expanded to derive outputs from the existing calculated results and to conditionally format report outputs according to the clinical user's preferences.

Performance Data [21 CFR 807.92(b)]

Summary of bench tests (non-clinical) conducted for determination of substantial equivalence [21 CFR 807.92(b)(1)]

Software verification and validation testing was completed to demonstrate functionality of the device across multiple datasets that had not been used to train any of the AI models. The same methodology was utilized for the performance qualification (PQ) tests for both Spine CAMP 1.1 and its primary component, the AI Engine v3.2, as had been previously utilized for the predicate device, Spine CAMP v1.0 and its primary component, the AI Engine v3.1. The software functioned as intended and all results observed were as expected.

Additional bench testing was performed by evaluating Spine CAMP™ v1.1 performance on a large dataset that was previously analyzed by Spine CAMP™ v1.0. Additionally, this dataset was analyzed by five experienced operators using the reference device, QMA, for spinopelvic measurements that Spine CAMP™ v1.0 was not designed to produce. This dataset included 215 lateral cervical spine

radiographs and 232 lateral lumbar spine radiographs. Statistical correlations and equivalence tests were performed by directly comparing vertebral landmark coordinates, image calibration, and intervertebral measurements between Spine CAMP™ v1.1 and the predicate device as well as spinopelvic measurements between Spine CAMP™ v1.1 and the reference device. This analysis demonstrated correlation and statistical equivalence for all variables evaluated.
Summary of clinical tests conducted for determination of substantial equivalence or of clinical information [21 CFR 807.92(b)(2)]
This section is not applicable to this submission. Clinical Data are not included.
Conclusions drawn [21 CFR 807.92(b)(3)]
Spine CAMP™ is as safe and effective as the predicate device. The subject device has the same intended use and indications for use as its predicate device. Their technological characteristics and principles of operations are nearly identical. The minor differences between the subject and predicate devices (i.e., retrained AI models and enhanced reporting capabilities) do not raise new or different questions regarding safety and effectiveness when used as labeled. The same performance testing methodology that was used utilized to test the subject device as had been used to test the predicate device. Specifically, for a large dataset of images, the subject device and the predicate device produced outputs that were statistically equivalent.