DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Ortho Kinematics, Inc.
% John J. Smith, M.D., J.D.
Regulatory Counsel
Hogan Lovells US LLP
555 13th Street, NW
WASHINGTON DC 20004

August 25, 2017

Re: K172327
Trade/Device Name: VMA System™ version 3.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 1, 2017
Received: August 1, 2017

Dear Dr. Smith:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael D. O'Hara For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: 6/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K172327

Device Name

VMA™ System version 3.0

Indications for Use *(Describe)*

The VMA software is a quantitative imaging software application intended to be used to process any diagnostic imaging modality except mammography from digital image files in DICOM format. It is designed for physicians and clinical professionals who are interested in the analysis of alignment and motion in medical images, particularly in musculoskeletal images of the spine. VMA software permits users to review static and dynamic digital lumbar, thoracic, and cervical spine images. In the case of fluoroscopic images, these are acquired with the assistance of the MOTION NORMALIZER patient handling and data collection device, which is designed for use by imaging technicians and intended to assist with patient lumbar and cervical bending and data collection during imaging. VMA software also facilitates quantitative assessment of vertebral alignment and motion in digital medical images. Information about the alignment and motion of selected objects, such as bone structures, can be generated and presented in the form of a 'motion analysis' report containing graphics, charts, and text.

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.

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510(k) SUMMARY

Ortho Kinematics, Inc. VMA™ System

Submitter

Ortho Kinematics, Inc.
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Phone: (512) 334-5490
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Contact Person: Adam Deitz, Chief Technology Officer

Date Prepared: August 18, 2017

Name of Device: VMA™ System version 3.0

Classification Name: Picture archiving and communications system (21 C.F.R. 892.2050)

Regulatory Class: Class II

Product Code: LLZ

Predicate Device

Ortho Kinematics, Inc.'s VMA System, version 2.2 (K133875)

Device Description

The subject device consists of the following components and accessories: VMA™ software (for data transfer, post-image processing and analysis), and its accessory device, the MOTION NORMALIZER™ patient handling and data collection device, which is comprised of the MOTION NORMALIZER Upright and Table devices (for patient assistance during image acquisition), and Control Console (for user interface during imaging).

The subject VMA™ software, and its accessory device, the MOTION NORMALIZER patient handling and data collection device, operate as a system ("the VMA™ System") in conjunction with other commercially-available accessory devices to produce quantitative analysis of inter-vertebral motion in adult patients.

None of the software associated with the subject device performs functions that create radiographic images, nor does the software control, operate, or govern the functionality of the imaging device (i.e., C-Arm Fluoroscopy Device).

With respect to the MOTION NORMALIZER™ hardware, this hardware is configured to assist with lumbar and cervical data collection while images are captured with a standard fluoroscope, and this remains unchanged in the modified device relative to the cleared system (K133875). The additional inclusion of the ability to process thoracic images in the

modified device pertains to a new ability to process thoracic images that come from a source other than the MOTION NORMALIZER™ hardware.

Image processing operators, who are Ortho Kinematics, Inc. employees, operate the VMA™ software to process images and facilitate template placement for the prescriber. Prescriber users are able to access processed images and measurement results via an online account administered by Ortho Kinematics, Inc. Prescriber users are able to configure account settings that enable the prescriber to be alerted any time specific user-defined measurement thresholds are exceeded.

Intended Use / Indications for Use

The VMA software is a quantitative imaging software application intended to be used to process any diagnostic imaging modality except mammography from digital image files in DICOM format. It is designed for physicians and clinical professionals who are interested in the analysis of alignment and motion in medical images, particularly in musculoskeletal images of the spine. VMA software permits users to review static and dynamic digital lumbar, thoracic, and cervical spine images. In the case of fluoroscopic images, these are acquired with the assistance of the MOTION NORMALIZER patient handling and data collection device, which is designed for use by imaging technicians and intended to assist with patient lumbar and cervical bending and data collection during imaging. VMA software also facilitates quantitative assessment of vertebral alignment and motion in digital medical images. Information about the alignment and motion of selected objects, such as bone structures, can be generated and presented in the form of a 'motion analysis' report containing graphics, charts, and text.

Summary of Technological Characteristics

The cleared and modified VMA Systems are substantially equivalent with the similarities and minor differences noted in the comparison table below:

	Ortho Kinematics, Inc.'s VMA™ Software and MOTION NORMALIZER System, Version 2.2 (K133875)	**Ortho Kinematics, Inc.'s VMA™ Software and MOTION NORMALIZER System, Version 3.0 (additions are underlined)**
Classification Name	System, Image Processing, Radiological	System, Image Processing, Radiological
Product Code	LLZ	LLZ
Required OTS Components for Image Acquisition	• Fluoroscope • Radiological Table • Fixed Media • Access to an internet connected computer terminal installed with internet browsing software	If MOTION NORMALIZER is being used • Fluoroscope • Radiological Table • Fixed Media • Access to an internet connected computer terminal installed with internet browsing software If MOTION NORMALIZER is NOT being used, then there are no required accessories for image acquisition.

	Ortho Kinematics, Inc.'s VMA™ Software and MOTION NORMALIZER System, Version 2.2 (K133875)	**Ortho Kinematics, Inc.'s VMA™ Software and MOTION NORMALIZER System, Version 3.0 (additions are underlined)**
Digital Image Processing Function	Digitizes analog fluoroscopy video feeds to enable digital image processing Utilizes a manual vertebral body templating process, plus a semi-automated tracking process	Digitizes analog fluoroscopy video feeds to enable digital image processing <u>Utilizes a semi-automated vertebral body templating process, plus a manual tracking process</u>
Assists w/ Lying vs. Standing Postures	Standing and Lying	Standing and Lying
Range of Assisted Lumbar Articulation	Maximum achievable lumbar AND cervical bending range = -40° to +60°	Maximum achievable lumbar AND cervical bending range = -40° to +60°
User/Operator During Imaging	Credential radiation technologists (AART) or other clinical professionals credentialed to operate a fluoroscope	Credential radiation technologists (AART) or other clinical professionals credentialed to operate a fluoroscope
Materials of Patient Handling Device	• Welded tube and sheet stainless steel; • Standard powder coating; • Standard ABS plastic; • 4-way nylon stretch fabric; • Vinyl covered synthetic leather.	• Welded tube and sheet stainless steel; • Standard powder coating; • Standard ABS plastic; • 4-way nylon stretch fabric; • Vinyl covered synthetic leather.
Dimensions of Component Occupying the Plane Perpendicular to Imaging Beam	Table: 87" x 52" Upright: 80" x 45"	Table: 87" x 52" Upright: 80" x 45"

Required OTS components	Image review workstation (PC):
	• Process: Pentium 4 equivalent or better
	• Ram Memory: 4 GB
	• Monitor: Resolution of 1280x800 pixels or greater suitable for medical diagnostic image review
	• Required installed software
	  ○ Internet Browser i.e. Internet Explorer, Firefox, etc. that supports HTML5
		Image review workstation (PC):
		• Process: Pentium 4 equivalent or better
		• Ram Memory: 4 GB
		• Monitor: Resolution of 1280x800 pixels or greater suitable for medical diagnostic image review
		• Required installed software
		  ○ Internet Browser i.e. Internet Explorer, Firefox, etc. that supports HTML5

User/Operator	Physicians and clinical professionals	Physicians and clinical professionals

	Ortho Kinematics, Inc.'s VMA™ Software and MOTION NORMALIZER System, Version 2.2 (K133875)	Ortho Kinematics, Inc.'s VMA™ Software and MOTION NORMALIZER System, Version 3.0 (additions are underlined)
Input Data Files	• DICOM files created using the MOTION NORMALIZER System	• DICOM files created using the MOTION NORMALIZER System • DICOM files generated using any modality.
Key Functionality	• Load image data • Display & Playback • Enhance Contrast • Put templates on anatomy • Auto and manual templating features • Forced manual review • Quantitative graphical output report generation	• Load image data • Display & Playback • Edit DICOM header data • Enhance Contrast • Put templates on anatomy • Auto and manual templating features • Forced manual review • Quantitative graphical output report generation
Quantitative Analysis & Measurement	• IVR & IVT measurements for lumbar and cervical motion • Image registration & tracking • Clinical Reporting • Calibration of translation data	• IVR & IVT measurements for lumbar and cervical motion • Alignment measurements, including millimeter based "Sagittal Vertical Axis" measurements plus a range of angular measurements • Image registration & tracking • Clinical Reporting • Calibration of translation data • Grid correction for fluoroscopic images

Performance Data

The VMA™ software and its accessory device, the MOTION NORMALIZER, have been designed and developed in accordance with FDA regulations, including validation and verification testing per FDA recognized standards, such as the following:

- IEC 60601-1: Medical Electrical Equipment- Part 1: General requirements for Basic Safety and Essential Performance (2012).
- IEC 60601-1-2: Medical Electrical Equipment - Part 1-2: General requirements for safety - Collateral Standard: Electromagnetic Compatibility - requirements and tests (2007).
- IEC 60601-1-3: Medical electrical equipment. Part 1: General requirements for safety; Part 1-2: Collateral Standard: Radiation protection in diagnostic X-ray equipment (2013).
- IEC 60601-1-6: Medical electrical equipment. Part 1: General requirements for safety; Part 1-4: Collateral Standard: Usability (2013).
- IEC 60601-2-54: Medical electrical equipment. Part 2: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy (2009).
- NEMA PS 3.1 – 3.20: Digital Imaging and Communications in Medicine (DICOM) Set (2017).

In addition, repeatability and accuracy testing was performed for the integrated system. In all instances, the subject system functioned as intended. Lastly, software validation testing was performed and documentation was provided for moderate level of concern software.

Substantial Equivalence Conclusion

The VMA™ software and its accessory device, the MOTION NORMALIZER, have the same intended use and similar indications for use, technological characteristics, and principles of operation as the company's own identified predicate device. The minor technological differences between the subject system and the predicate system raise no new or different questions of safety or effectiveness. Validation and verification data (including software validation) demonstrate that the subject device functions as intended, and performs functions substantially equivalent to the predicate device. Thus, the subject device is substantially equivalent.