510(k) SUMMARY

ORTHO KINEMATICS, INC.

JAN 1 7 2014

INTEGRATED SYSTEM COMPRISED OF THE KINEGRAPH VMA™ (VERTEBRAL MOTION ANALYZER) SOFTWARE AND ITS ACCESSORY DEVICE, THE MOTION NORMALIZER IMAGE™ PATIENT HANDLING AND DATA COLLECTION DEVICE (VERSION 2.2)

SUBMITTED BY

John Smith, M.D, J.D.
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CONTACT PERSON

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DATE PREPARED

December 20, 2013

DEVICE PROPRIETARY NAME

The integral system comprised of:
- the KINEGRAPH VMA™ (VERTEBRAL MOTION ANALYZER) software (version 2.0), and its accessory device,
- the MOTION NORMALIZER™ patient handling and data collection device (version 2.0)

DEVICE COMMON NAME

The VMA system; the MOTION NORMALIZER device

CLASSIFICATION NAME / PRODUCT CODE

System, Image Processing, Radiological / LLZ

DEVICE CLASS

Class II

REGULATION NUMBER

21 C.F.R. 892.2050

PREDICATE DEVICE

Version 2.0 of the VMA system (K130743)

PURPOSE OF THE SPECIAL 510K NOTICE

Version 2.2 of the VMA system is a modification to version 2.0 of the system, which was the originally cleared version.

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INTENDED USE

The KINEGRAPH VMA™ software is a quantitative imaging software application intended to be used to process digital image files. It is designed for physicians and clinical professionals who are interested in the analysis of motion in medical images, particularly in musculoskeletal images of the spine. KINEGRAPH VMA™ software permits users to review static and dynamic digital lumbar and cervical spine images 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. KINEGRAPH VMA™ software also facilitates quantitative assessment of vertebral motion in digital medical images. Information about the 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.

TECHNOLOGICAL CHARACTERISTICS

The subject device consists of the KINEGRAPH VMA™ software that analyzes images from the MOTION NORMALIZER™ on an Off-the-Shelf ("OTS") imaging workstation. The MOTION NORMALIZER patient handling and data collection device is an accessory device to the KINEGRAPH VMA™ software that is used to assist with subject lumbar bending and data collection while images are captured with a standard fluoroscope. The MOTION NORMALIZER is comprised of two powered, electromechanical patient handling devices connected to and controlled by a console-mounted OTS computer running custom software connected to various OTS hardware accessories. The subject system is able to capture and record radiographic image data, as well as data from the patient handling devices, and to output this data into DICOM compatible digital image files for analysis using the KINEGRAPH VMA™ software. Once images have been created, they can be uploaded to online servers using running KINEGRAPH VMA™ software using an internet connected computer. All software operation and data storage that occurs subsequent to uploading occurs via online servers running KINEGARPH VMA software. Image processing operators, who are Ortho Kinematics, Inc. employees, operate the KINEGRAPH VMA™ software to process images and facilitate template placement for the prescriber. Prescriber users are able to access processed image 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.

PERFORMANCE DATA

The KINEGRAPH 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. In addition, repeatability and accuracy testing was performed for the integrated system. In all instances, the KINEGRAPH VMA™ software and its accessory device, the MOTION NORMALIZER™, functioned as intended.

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SUBSTANTIAL EQUIVALENCE

The KINEGRAPH VMA™ software and its accessory device, the MOTION NORMALIZER™, has the same intended use and indications for use, technological characteristics, and principles of operation as the identified predicate device. The minor technological differences between the KINEGRAPH VMA™ software and its accessory device, the MOTION NORMALIZER™, and the predicate device raise no new issues 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.

	KineGraph VMA™ System v2.2 (subject device)	KineGraph VMA™ System v2.0 (K130743, the cleared device)
Classification Name	System, Image Processing, Radiological	System, Image Processing, Radiological
Product Code	LLZ	LLZ

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	KineGraph VMA™ System v2.2 (subject device)	KineGraph VMA™ System v2.0 (K130743, the cleared device)
Indications for Use	The KINEGRAPH VMA™ software is a quantitative imaging software application intended to be used to process digital image files. It is designed for physicians and clinical professionals who are interested in the analysis of motion in medical images, particularly in musculoskeletal images of the spine. KINEGRAPH VMA™ software permits users to review static and dynamic digital lumbar and cervical spine images 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. KINEGRAPH VMA™ software also facilitates quantitative assessment of vertebral motion in digital medical images. Information about the 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.	The KINEGRAPH VMA™ software is a quantitative imaging software application intended to be used to process digital image files. It is designed for physicians and clinical professionals who are interested in the analysis of motion in medical images, particularly in musculoskeletal images of the spine. KINEGRAPH VMA™ software permits users to review static and dynamic digital lumbar and cervical spine images 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. KINEGRAPH VMA™ software also facilitates quantitative assessment of vertebral motion in digital medical images. Information about the 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.
Technological Characteristics / Functionality	• Lumbar, cervical intervertebral motion measurements • Lumbar, cervical device assisted bending	• Lumbar, cervical intervertebral motion measurements • Lumbar, cervical device assisted bending
Principles of Operation	• Produce digital imaging output files with the use of the MOTION NORMALIZER device in combination with a standard, commercially available fluoroscope and standard radiological procedure table. • KineGraph VMA™ Image Processing software is operated by Ortho Kinematics, Inc. staff as a service to facilitate template placement for prescriber users. • Transfer output files from the MOTION NORMALIZER device to	• Produce digital imaging output files with the use of the MOTION NORMALIZER device in combination with a standard, commercially available fluoroscope and standard radiological procedure table. • KineGraph VMA™ Image Processing software is operated by Ortho Kinematics, Inc. staff as a service to facilitate template placement for prescriber users. • Transfer output files from the MOTION NORMALIZER device to

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	KineGraph VMA™ System v2.2 (subject device)	KineGraph VMA™ System v2.0 (K130743, the cleared device)
	the company by uploading to a server using the KineGraph VMA™ DataLink Software. • KineGraph VMA™ Image processing and Image Review software, as well as patient results which have been processed by Ortho Kinematics, Inc., are available via any internet connected computer terminal running installed with internet browsing software. • Prescribers can use online user accounts to store alert preferences, such that they can be alerted upon login whenever patient results exceed the user-defined thresholds.	the Company using removable media that is shipped to the Company. • KineGraph VMA™ Image processing software runs on standard off-the-shelf image review workstations installed with certain specific off the shelf software (Matlab runtime compiler, Microsoft Excel, others) • Patient results transferred from the company to the prescriber via removable media. • KineGraph VMA™ Image Review software runs on standard off-the-shelf image review workstations installed with certain specific off the shelf software (Adobe Flash, ghostscript, others) • No alerting features.

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January 17, 2014

Ortho Kinematics, Inc.
% John Smith, M.D., J.D.
Hogan Lovells US LLP
555 13th Street, NW
WASHINGTON DC 20004

Re: K133875
    Trade/Device Name: KineGraph VMA™ (Vertebral Motion Analyzer) Software, and the
                       Motion Normalizer™ Patient Handling and Data Collection Device
                       (Version 2.2)
    Regulation Number: 21 CFR 892.2050
    Regulation Name: Picture archiving and communications system
    Regulatory Class: II
    Product Code: LLZ
    Dated: December 20, 2013
    Received: December 20, 2013

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

for

Janine M. Morris
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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K133875

Device Name
KINEGRAPH VMA™ (VERTEBRAL MOTION ANALYZER) and MOTION NORMALIZER (version 2.2)

Indications for Use *(Describe)*

The KineGraph VMA™ software is a quantitative imaging software application intended to be used to process digital image files. It is designed for physicians and clinical professionals who are interested in the analysis of motion in medical images, particularly in musculoskeletal images of the spine. KineGraph VMA™ software permits users to review static and dynamic digital lumbar and cervical spine images 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. KineGraph VMA™ software also facilitates quantitative assessment of vertebral motion in digital medical images. Information about the 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.
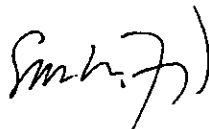
Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D)   ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

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