DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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August 22, 2017

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

Re: K171617
Trade/Device Name: OKI Surgical Planning Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 11, 2017
Received: August 11, 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: 06/30/2020
See PRA Statement below

510(k) Number *(if known)*
K171617

Device Name

OKI Surgical Planning Software

Indications for Use *(Describe)*

The OKI Surgical Planning Software assists healthcare professionals in planning lumbar spinal fusion surgeries. The device allows service providers to plan surgical procedures, including tools for assessing anatomical components for placement of surgical implants. Clinical judgment and experience are required to properly use the software.

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
(K171617)

Ortho Kinematics, Inc.'s OKI Surgical Planning Software

Submitter

Ortho Kinematics, Inc.
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Contact Person: Adam Deitz, Chief Technology Officer

Date Prepared: August 11, 2017

Name of Device: OKI Surgical Planning Software

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

Regulatory Class: Class II

Product Code: LLZ

Predicate Device: Nemaris, Inc.'s Surgimap 2.0 (K141669)

Device Description

The Ortho Kinematics OKI Surgical Planning Software is a software only accessory to a picture archiving and communications system. It is designed to be used to assess measurements from DICOM compliant images in a cleared PACS device and plan surgical spinal procedures. It offers the ability to plan certain surgical procedures, such as lumbar spine fusion. It offers tools for viewing data, and the ability to facilitate the estimation of a potential post-operative alignment and correction, based on pre-operative measurements, as well as the geometric parameters associated with specific lumbar interbody implant devices.

Intended Use / Indications for Use

The OKI Surgical Planning Software assists healthcare professionals in planning lumbar spinal fusion surgeries. The device allows service providers to plan surgical procedures, including tools for assessing anatomical components for placement of surgical implants. Clinical judgment and experience are required to properly use the software

Comparison of Technological Characteristics

The following table provides a comparison of technological characteristics to the predicate device:

Feature	OKI Surgical Panning Software	Surgimap 2.0
Computer	PC Compatible	PC Compatible
Operating System	Windows + MAC	Windows + MAC
Image Input	No image input; measurements from DICOM compliant images inputted from cleared PACS	Local + PACS connectivity
Runs on Server	Optional	Yes
Generic measurements	Yes	Yes
Spine measurements	Yes	Yes
Pre-operative planning	Yes	Yes
Custom implants	No	Yes
Database of implants	Yes	Yes
Case sharing	No	Yes
Human Intervention for interpretation and manipulation of images	Required	Required

Performance Data

Software verification and validation testing was completed for the subject device. The software functioned as intended and all results observed were as expected.

Conclusions

The OKI Surgical Planning Software is as safe and effective as the predicate device. The subject device has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences in indications do not alter the intended therapeutic use of the device and do not affect its safety and effectiveness when used as labeled. In addition, the minor technological differences between the subject device and its predicate device raise no different questions of safety or effectiveness. Software verification and validation testing demonstrates that the device performs as intended. Thus, the Surgical Planning Software is substantially equivalent.