Ortho Kinematics, Inc.
% John Smith, M.D., J.D.
Regulatory Counsel
Hogan Lovells US LLP
553 13th Street, NW
WASHINGTON DC 20004

November 8, 2017

Re: K173247
Trade/Device Name: Surgical Planning Software version 1.1
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: October 6, 2017
Received: October 6, 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K173247

Device Name

Surgical Planning Software version 1.1

Indications for Use *(Describe)*

The 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.

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510(k) SUMMARY

K173247

Ortho Kinematic, Inc.'s Surgical Planning Software version 1.1

Submitter

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

Date Prepared: November 6, 2017

Name of Device: Surgical Planning Software version 1.1

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 Surgical Planning Software version 1.1 (K171617)

Device Description

The Ortho Kinematics 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 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	Surgical Planning Software version 1.1	Surgical Planning Software version 1.0
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	No image input; measurements from DICOM compliant images inputted from cleared PACS
Runs on Server	Optional	Optional
Generic measurements	Yes	Yes
Spine measurements	Yes	Yes
Display of geometric and measurement data	Graphical and Textual	Textual
Pre-operative planning	Yes	Yes
Custom implants	No	No
Database of implants	Yes	Yes
Case sharing	No	No
Access to VMA report PDF and associated data	Yes	No
Output file formats	JSON and PDF file output	JSON file output
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 Surgical Planning Software is as safe and effective as the predicate device. The subject device has the same intended use and indications for use with similar technological characteristics and principles of operation as its predicate device. 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.