DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 21, 2017

Kico Knee Innovation Company PTY Limited
% Mr. Sandy Hedberg
Partner
SoftwareCPR
448 Mariner Point Drive
CLINTON TN 37716

Re: K163405
Trade/Device Name: 360KS Implant Positioning System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 17, 2017
Received: February 23, 2017

Dear Mr. Hedberg:

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 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 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

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 below.

510(k) Number *(if known)*
K163405

Device Name
360KS Implant Positioning System

Indications for Use *(Describe)*
360KS Implant Positioning System (IPS) is intended for use as patient-specific surgical planning software to aid orthopaedic surgeons in selection, sizing and placement of knee implant components (femur, tibia and patella implants) provided that the required anatomical landmarks of the knee can be identified on pre-operative CT or MRI scans in patients requiring total knee arthroplasty.

360KS IPS is indicated for use with OMNI Life Science Apex Knee System (#K060192, #K073602, #K080842) and Corin Unity Total Knee System (#K113060).

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

1. 510(K) SUMMARY

1.1 APPLICANT/SPONSOR DISTRIBUTOR

360 Knee Systems
Capital Factory
701 Brazos St, Suite 500
Austin, TX 78701
United States
Establishment Registration No: None

1.2 MANUFACTURER

Kico Knee Innovation Company Pty Ltd.
Suite 3, Building 1, 20 Bridge Street
Pymble NSW 2073
AUSTRALIA
Establishment Registration No: None

1.3 CONTACT PERSON

Sandy Hedberg
Partner
Phone: 865-463-0572
Email: shedberg@softwarecpr.com

1.4 DATE PREPARED

November 5, 2016

1.5 DEVICE

Name of Device: 360KS Implant Positioning System

Common Name: Image Management Software

Classification Name: 21 CRF 892.2050 – Picture archiving and communications system

Regulatory Class: II

Product Code: LLZ

1.6 DEVICE DESCRIPTION

360KS Implant Positioning System (project name KicoCAD) is a medical device consisting of a software application that provides patient-specific pre-operative surgical planning to assist in the positioning of knee implant components (femur, tibia and patella implants) with compatible knee systems (OMNI Life Science Apex Knee System (#K060192, #K073602, #K080842) and Corin Unity Total Knee System (#K113060)) for total knee arthroplasty.

The software is designed to assist qualified medical professionals with implant component placement, orientation, positioning and size selection. 360KS Implant Positioning System uses a Graphical User Interface (GUI), where any input provided by the user will provide visual feedback reflecting the input provided. Pre-operative plans are available for the femur, tibia and patella.

360KS Implant Positioning System (360KS IPS) requires access to pre-processed patient images (CT or MRI scan) to display three-dimensional images. Pre-processing is done by the engineering team of Kico Knee Innovation Company using Scan IP (510(k) accession number: K142779) to generate a three-dimensional bone model and landmarks. The bone model and landmarks are then imported into 360KS IPS and Production Engineers of Kico Knee Innovation Company apply the referring surgeon's prescription for sizing and placement of femoral, tibia and patella components to generate a surgical plan. The process of landmarking and surgical plan creation both have independent QC steps. Once the plan is complete and all QC steps have passed, it is uploaded to the cloud and made available to the referring surgeon. The referring surgeon can then view and modify the plan on their own installation of 360KS Implant Position System.

The 360KS Implant Positioning System is developed within the Integrated Development Environment (IDE) of Visual Studio Professional. The software is written in C# (C Sharp) using .NET framework target version 4.5 in Windows Operating System (OS). 360KS Implant Positioning System is recommended to run on a Windows 7 PC with 2.4 GHz or faster intel Core i5-6300 processor for best performance. The 360KS Implant Positioning System requires 4GB of RAM and a DirectX 9 graphics device with WDDM 1.0 or higher driver. The application requires 10GB of available disk space and the visual display resolution should be set to 1920x1080. An internet connection is also required.

The intended users are production trained engineers and trained orthopaedic surgeons who have experience in total knee replacement. To ensure correct user operation of the software, 360KS Implant Positioning System incorporates simple UI design to make the software more intuitive.

Creation of patient specific guides from the surgical plan is neither part of this device nor submission.

1.7 INTENDED USE / INDICATIONS

360KS Implant Positioning System (IPS) is intended for use as patient-specific surgical planning software to aid orthopaedic surgeons in selection, sizing and placement of knee implant components (femur, tibia and patella implants) provided that the required anatomical landmarks of the knee can be identified on pre-operative CT or MRI scans in patients requiring total knee arthroplasty.

360KS IPS is indicated for use with OMNI Life Science Apex Knee System (#K060192, #K073602, #K080842) and Corin Unity Total Knee System (#K113060).

1.8 COMPARISON OF TECHNICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Manufacturer	Device	510(k) Number
Lexi	ZedView	K133022

360KS Implant Positioning System is considered to be substantially equivalent to ZedView (K133022) from Lexi. The two devices provide capabilities for total knee replacement surgical planning.

At a higher level, the subject and the predicate devices are based on the same technological elements:

- Visualisation and 3D bone model generation using DICOM file
- Surgical planning in a 3D environment, including templating and positioning of implants
- Storage and retrieval of plan file for future use

While the technology used in both subject and predicate devices are identical, there are several feature differences:

- Image format - ZedView provides pre-operative planning from CT image while 360KS Implant Positioning System provides pre-operative planning from CT and MRI images. Note MRI image segmentation is provided by use of OTS Software ScanIP (510(k) #K142779).

1.9 PERFORMANCE DATA

The following performance data are provided in support of the substantial equivalence determination:

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for the Industry and FDA Staff: 'Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.' Testing included both system and unit level.

The software for this device is considered a 'Moderate' level of concern (see section 18.1 for assessment), as, prior to mitigation of hazards, a failure of the device could result in minor injury. A failure or misuse of ScanIP (510(k) #K142779), such as misinterpreting scanned data, could in exceptional circumstances cause a minor injury to a patient. This could take the form of implant components being incorrectly positioned. Software documentation, including verification and validation activities and related performance data, has been provided to demonstrate that appropriate steps have been taken to ensure mitigation of potential risks.

1.10 NON-CLINICAL TESTING

Non-clinical testing in the form of software verification and validation were performed to assess the safety and effectiveness of the device. The testing verified that the accuracy and performance of the system is adequate to perform as intended.

1.11 CLINICAL TESTING

This section does not apply. Clinical testing is not required for this Traditional 510(k) device.