January 11, 2022

Kico Knee Innovation Company Pty Limited
Stefanie Auf Der Mauer
Head of RA/QA
Suite 3, Building 1, 20 Bridge Street
Pymble, New South Wales 2073
Australia

Re: K213380
Trade/Device Name: 360cas
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: October 8, 2021
Received: October 13, 2021

Dear Stefanie Mauer:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*
K213380

Device Name
360CAS

Indications for Use *(Describe)*
The 360CAS is intended to be used as a planning and intraoperative guidance system to enable open or percutaneous image guided surgical procedures.

The 360CAS is indicated for patients undergoing orthopaedic surgery and where reference to a rigid anatomical structure, such as the pelvis, femur, or tibia, can be identified.

The 360CAS Knee is indicated for the following surgical procedures:
- Total Knee Arthroplasty (TKA)
- For conditions of the knee joint in which the use of computer assisted surgery may be appropriate

The 360CAS Hip is indicated for the following surgical procedures:
- Total Hip Arthroplasty (THA) e.g., open or minimally invasive, where a posterior or anterior approach is used
- For conditions of the hip joint in which the use of computer assisted surgery may be appropriate

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

A 510(k) summary has been prepared in accordance with the requirements of 21 CFR 807.92 Content and Format of a 510(k) Summary.

Applicant Details

Name:	Kico Knee Innovation Company Pty Limited
Address:	Suite 3, Building 1, 20 Bridge Street
	Pymble, New South Wales 2073
	Australia
Contact Person / Prepared By:	Emma Hayes
	Regulatory Affairs Manager
	+64 221 188 373 (phone)
	emma@360med.care
Date Prepared:	January 11, 2022

Device Details and Substantial Equivalence Claim

Device Common Name:	Orthopedic Stereotaxic Instrument	
Device Trade Name:	360CAS	
Regulation Number:	21 CFR 882.4560	
Regulation Name:	Stereotaxic Instrument	
Regulatory Class:	II	
Panel:	Orthopedic	
Product Code:	OLO	
Predicate Devices: (Primaries for Knee and Hip)	Stryker OrthoMap Precision Knee System (K162341)	Stryker OrthoMap Versatile Hip System (K162937)

Device Description

The 360 Computer Assisted Surgery (360CAS) is a stereotaxic surgical navigation system for orthopaedic surgical procedures. The 360CAS is intended to be used as a planning and intraoperative guidance system with any manufacturers implant in open or percutaneous orthopaedic surgical procedures. The 360CAS uses optical tracking technology that allows surgeons to map a patient's morphology, navigate surgical instruments and implants and assess the state of the joint throughout the surgery. The system consists of four main components: 360CAS navigation software, which consists of two modules: 360CAS Knee and 360CAS Hip, surgical instruments, spatial tracking components and a navigation cart. 360CAS Knee is a 360CAS navigation software for knee replacement surgery. 360CAS Hip is a 360CAS navigation software for hip replacement surgery. The navigation software interfaces with the optical trackers which are attached to navigation instruments (e.g. pointer, bone fixator(s)).

Indications for Use

The 360CAS is intended to be used as a planning and intraoperative guidance system to enable open or percutaneous image guided surgical procedures.

The 360CAS is indicated for patients undergoing orthopaedic surgery and where reference to a rigid anatomical structure, such as the pelvis, femur, or tibia, can be identified.

The 360CAS Knee is indicated for the following surgical procedures:

- Total Knee Arthroplasty (TKA)
- For conditions of the knee joint in which the use of computer assisted surgery may be appropriate

The 360CAS Hip is indicated for the following surgical procedures:

- Total Hip Arthroplasty (THA) e.g., open or minimally invasive, where a posterior or anterior approach is used
- For conditions of the hip joint in which the use of computer assisted surgery may be appropriate

Performance Data

The following performance data was provided in support of substantial equivalence decision:

Electrical Safety and Electromagnetic Compatibility (EMC) Testing

Electrical safety and EMC testing were conducted on the subject device in accordance with the following standards:

- AS/NZS 3551:2012 Management Programs for Medical Equipment
- IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests (FDA Recognition #: 19-8)

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by:

- Guidance for Industry and Food and Drug Administration Staff: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices issued 11-May-2005
- Guidance for Industry and Food and Drug Administration Staff: Off-the-Shelf Use in Medical Devices issued 27-Sep-2019

The 360CAS Navigation Software was considered as a "MAJOR" level of concern.

Performance Testing – Bench

The following design verification and validation activities have been performed to ensure the correct functionality of the system as it has been specified:

- ASTM accuracy testing verifying the accuracy performance of the spatial tracking technology using the standardized test procedure according to ASTM F2554-18.
- System accuracy testing verifying the specified accuracy of ±2mm and ±1° using Sawbones mimicking patient's anatomy.
- Clinical accuracy testing verifying the specified accuracy of ±3mm and ±3° in a cadaveric laboratory.
- Clinical workflow verifying that all system components (application, computer platform and accessories) are compatible. Complete knee and hip arthroplasty procedures were simulated using Sawbones mimicking the patient's anatomy and cadaver laboratory.
- Functional testing to ensure that all functional requirements are fulfilled.

- Safety testing verifying the effectiveness of all risk controls determined in the device risk analysis.

This strategy ensures the verification of the accuracy, system integration, software algorithms, system functionality, and correct implementation of the risk control measures. All tests have been successfully completed.

Animal Study

No animal studies were performed to support substantial equivalence.

Clinical Studies

No clinical studies were performed to support substantial equivalence.

Substantial Equivalence Rationale - 360CAS Knee

The 360CAS Knee is considered substantially equivalent to the Stryker OrthoMap Precision Knee System regarding clinical, technical, and biological characteristics. The 360CAS Knee and the Stryker OrthoMap Precision Knee System are both intended to be used as planning and intraoperative guidance systems to enable open and percutaneous surgical procedures. Both systems are indicated for knee conditions where the use of CAS is appropriate (e.g., TKA) and where reference to a rigid anatomical structure can be identified. The 360CAS Knee and the Stryker OrthoMap Precision Knee System are intended to be used by trained orthopaedic surgeons and operators in an equivalent fashion, following equivalent registration and navigation workflows. Both systems comprise equivalent components (computer platform, navigation software, instruments, tracking components) to achieve the same purpose. The 360CAS Knee and Stryker OrthoMap Precision Knee System both require AC power to power the computer, monitor and camera. The Stryker OrthoMap Precision Knee System requires additional external energy sources (batteries) to power their smart instruments, whereas the 360CAS Knee does not require additional external energy sources for its instruments. Both systems use optical tracking technology where a tracker is sensed by a camera to compute spatial information. Surgical navigation in both systems is enabled through similar software platforms developed by each manufacturer. The 360CAS Knee passive optical trackers and instruments do not require infrared (IR), wireless connection or external energy sources for operation. Such passive instruments are commonly used and have been successfully integrated in other marketed devices such as the K102251 BrainLAB DASH Knee. The 360CAS Knee and the Stryker OrthoMap Precision Knee System are measuring devices

with identical accuracy of ±2 mm and ±1°. Therefore, it is concluded that the 360CAS Knee is substantially equivalent to the Stryker OrthoMap Precision Knee System.

Characteristic	**360CAS Knee** (Subject Device)	**Stryker OrthoMap Precision Knee System** (Predicate Device)
Trade Name:	360CAS Knee	Stryker OrthoMap Precision Knee System
510(k) Submitter:	Kico Knee Innovation Company Pty Limited	Stryker Leibinger GmbH & Co. KG
510(k) Number:	K213380	K162341
Regulation Number:	882.4560 – Stereotaxic Instrument	882.4560 – Stereotaxic Instrument
Product Code:	OLO	OLO
Product Class:	II	II
Indications for Use	The 360CAS is intended to be used as a planning and intraoperative guidance system to enable open or percutaneous image guided surgical procedures. The 360CAS is indicated for patients undergoing orthopaedic surgery and where reference to a rigid anatomical structure, such as the pelvis, femur, or tibia, can be identified. The 360CAS Knee is indicated for the following surgical procedures: • Total Knee Arthroplasty (TKA) • For conditions of the knee joint in which the	The Stryker OrthoMap Precision Knee system, which is comprised of the OrthoMap Precision Knee 5.0 software and a platform of the NAV3i platform family, is intended as a planning and intraoperative guidance system to enable open or percutaneous image guided surgery. The system can be used for intraoperative guidance where a reference to a rigid anatomical structure can be identified. The system is indicated for conditions of the knee joint in which the use of computer assisted surgery may be appropriate.

Characteristic	360CAS Knee (Subject Device)	Stryker OrthoMap Precision Knee System (Predicate Device)
	use of computer assisted surgery may be appropriate	
Anatomy	Knee	Knee
Patient Population	Patients with medical conditions where use of computer-assisted surgery may be appropriate.	Patients with conditions of the knee joint where use of computer-assisted surgery may be appropriate.
End-Users	Trained orthopaedic surgeon and system operators	Trained orthopaedic surgeon and system operators
Clinical Workflow	Clinical workflow testing verifying that all system components are compatible. Complete total knee arthroplasty procedures are simulated using Sawbones mimicking the patient's anatomy and cadaver laboratory.	Clinical workflow testing verifying that all system components (application, computer platform and accessories) are compatible. Complete total knee arthroplasty procedures are simulated using Sawbones mimicking the patient's anatomy.
Main System Components	Computer Platform Navigation Cart 360CAS Navigation Software - 360CAS Knee Surgical Instruments Spatial Tracking Components	Computer Platform OrthoMap Precision Knee 5.0 Software Smart Instruments Patient Tracker Fixation Navigated Manual Instruments Instrument Battery, Trays
Energy Source	Computer - AC Power	Computer – AC Power Smart Instruments – Battery 1. Pointer 2. nGenius® Tibia Tracker

Characteristic	**360CAS Knee** (Subject Device)	**Stryker OrthoMap Precision Knee System** (Predicate Device)
		3. nGenius® Femur Tracker
Tracking Technology	Passive optical tracking technology	Infrared optical active sensing technology: Infrared light emitted by diodes placed in a known fashion on navigated surgical instruments is sensed by a camera array (navigation camera) on the computer platform, thus allowing for computation of the spatial information.
Image Display	Monitor	Monitor
System Accuracy	The system enables the determination of the mechanical axes of the lower limb as well as cut and component alignment with a mean translational error of < ±2 mm and a mean rotational error of < ±1°.	The system enables the determination of the mechanical axes of the lower limb as well as cut and component alignment with a mean translational error of < ±2 mm and a mean rotational error of < ±1°.
Software	360CAS Navigation Software - 360CAS Knee	OrthoMap Precision Knee 5.0 Software
Patient / Instrument Trackers	<u>Patient/Instrument Trackers</u> • Femur Tracker • Tibia Tracker • Resection Guide Tool <u>Pointer</u> • Pointer	<u>Patient/Instrument Trackers</u> • Universal Tracker • Tibia/Pelvic Tracker • Femoral Tracker • nGenius Universal Tracker • nGenius Tibial Tracker • nGenius Femur Tracker • Hip Femur Tracker

Characteristic	**360CAS Knee** (Subject Device)	**Stryker OrthoMap Precision Knee System** (Predicate Device)
		• Hip Tibia/Pelvis Tracker <u>Pointers</u> • Pointer, Knee Navigation • Ortho Grip Knee Pointer
Patient Tracker Fixation	Bone Fixator	OrthoLock with OrthoLock Navigation Pin or OrthoLock EX-Pins Anchoring Pins and Insertion Tool
Navigated Manual Instruments	Resection Guide Tool The resection tool is capable of being used with any manufacturers cutting blocks. The resection guide tool is compatible with 1.3mm thick saw blades.	Dedicated Mini Jig (which consists of): • Adjustment Component • Tracker Adapter • Mini Cutting Guide • Mini Fixation Plate MIS Jig (which consists of): • Navigated MIS Jig-A • Navigated MIS Jig-B • Tracker Adapter Plane Probes (Resection Plan Probes and a Posterior Plane Probe)

Substantial Equivalence Rationale - 360CAS Hip

The 360CAS Hip is considered substantially equivalent to the Stryker OrthoMap Versatile Hip System regarding clinical, technical and biological characteristics. The 360CAS and the Stryker OrthoMap Versatile Hip System are both intended to be used as planning and intraoperative guidance systems to enable open and percutaneous surgical procedures. Both systems are indicated for hip conditions where the use of CAS is appropriate (e.g., THA) and reference to a rigid anatomical structure can be identified. The 360CAS Hip and the Stryker OrthoMap Versatile Hip System are intended to be used by trained orthopaedic surgeons and operators in an equivalent fashion, following equivalent registration and navigation workflows. Both systems comprise equivalent components (computer platform, navigation software, instruments, tracking components) to achieve the same purpose. The 360CAS Hip and Stryker OrthoMap Versatile Hip System both require AC power to power the computer, monitor and camera. The Stryker OrthoMap Versatile Hip System requires additional external energy sources (batteries) to power smart instruments, whereas the 360CAS Hip does not require additional external energy sources for its instruments. Both systems use optical tracking technology where a tracker is sensed by a camera to compute spatial information. The 360CAS Hip passive optical trackers and instruments do not require infrared (IR), wireless connection or external energy sources for operation. Such passive instruments are commonly used and have been successfully integrated in other marketed devices such as the K102251 BrainLAB DASH Knee. Surgical navigation in both systems is enabled through similar software platforms developed by each manufacturer. The 360CAS Hip and the Stryker OrthoMap Versatile Hip System are measuring devices where the 360CAS Hip provides greater accuracy of with mean translational error of <±2 mm and mean rotational error of <±1°. Therefore, it is concluded that the 360CAS Hip is substantially equivalent to the Stryker OrthoMap Versatile Hip System.

Characteristic	**360CAS Hip** (Subject device)	**Stryker OrthoMap Versatile Hip System** (Predicate device)
Trade Name:	360CAS Hip	Stryker OrthoMap Versatile Hip System

Characteristic	**360CAS Hip** (Subject device)	**Stryker OrthoMap Versatile Hip System** (Predicate device)
510(k) Submitter:	Kico Knee Innovation Company Pty Limited	Stryker Leibinger GmbH & Co. KG
510(k) Number:	K213380	K162937
Regulation Number:	882.4560 – Stereotaxic Instrument	882.4560 – Stereotaxic Instrument
Product Code:	OLO	OLO
Product Class:	II	II
Indications for Use	The 360CAS is intended to be used as a planning and intraoperative guidance system to enable open or percutaneous image guided surgical procedures. The 360CAS is indicated for patients undergoing orthopaedic surgery and where reference to a rigid anatomical structure, such as the pelvis, femur, or tibia, can be identified. The 360CAS Hip is indicated for the following surgical procedures: • Total Hip Arthroplasty (THA) e.g., open or minimally invasive, where a posterior or anterior approach is used • For conditions of the hip joint in which the use of computer assisted surgery may be appropriate	The Stryker OrthoMap Versatile Hip System, which is comprised of the OrthoMap Versatile Hip 2.0 Software and a platform of the NAV3i platform family, is intended as a planning and intraoperative guidance system to enable open or percutaneous image guided surgery. The system can be used for intraoperative guidance where a reference to a rigid anatomical structure such as but not limited to the pelvis, or femur, can be identified. The system is indicated for conditions of the hip joint in which the use of image guided surgery may be appropriate. The Stryker OrthoMap Versatile Hip system is indicated for the following surgical procedures: • Total Hip Athroplasty (THA), e.g. open or minimally-invasive • Precisely position instruments, implants and bony tissue during orthopedic hip surgery

Characteristic	360CAS Hip (Subject device)	Stryker OrthoMap Versatile Hip System (Predicate device)
		• Revisions.
Anatomy	Hip	Hip
Patient Population	Patients with conditions of the hip joint where use of computer-assisted surgery may be appropriate.	Patients with conditions of the hip joint where use of computer-assisted surgery may be appropriate.
End-Users	Trained orthopaedic surgeons and system operators	Trained orthopaedic surgeons and system operators
Clinical Workflow	Clinical workflow testing verifying that all system components are compatible. Complete total hip arthroplasty procedures are simulated using Sawbones mimicking the patient's anatomy and cadaver laboratory.	Clinical workflow testing verifying that all system components (application, computer platform and accessories) are compatible. Complete total hip arthroplasty procedures are simulated using Sawbones mimicking the patient's anatomy.
Main System components	Computer Platform Navigation Cart 360CAS Navigation Software - 360CAS Hip Surgical Instruments Spatial Tracking Components	Computer Platform OrthoMap Versatile Hip 2.0 Software Smart Instruments Patient Tracker Fixation Navigated Manual Instruments Instrument Battery, Trays
Energy Source	Computer - AC Power	Computer – AC Power Smart Instruments – Battery 1. Pointer 2. Patient Tracker, blue (Pelvis) 3. Pelvis Tracker, green (Femur) 4. Instrument Tracker

Characteristic	**360CAS Hip** (Subject device)	**Stryker OrthoMap Versatile Hip System** (Predicate device)
Tracking Technology	Passive optical tracking technology	Infrared optical active sensing technology: Infrared light emitted by diodes placed in a known fashion on navigated surgical instruments is sensed by a camera array (navigation camera) on the computer platform, thus allowing for computation of the spatial information.
Image Display	Monitor	Monitor
System Accuracy	The system enables the determination of the mechanical axes of the lower limb as well as cut and component alignment with a mean translational error of < ±2 mm and a mean rotational error of < ±1°.	The system enables the determination of the mechanical axes of the leg as well as cut and component alignment with a mean translational error of < 2 mm and a mean rotational error of < 2°.
Software	360CAS Navigation Software • 360CAS Hip	OrthoMap Precision Hip 2.0 Software
Patient / Instrument Trackers	<u>Patient/Instrument Trackers</u> • Pelvis Tracker • Femur Tracker • Tracker Universal Grip <u>Pointer</u> • Pointer	<u>Patient/Instrument Trackers</u> • Hip Femur Tracker • Hip Tibial/Pelvic Tracker • Instrument Tracker <u>Backup Trackers</u> • Universal Tracker • Tibial/Pelvic Tracker • Femoral Tracker <u>Pointers</u> • Pointer, Knee Navigation • Ortho Grip Knee Pointer • Hip Pointer, Straight

Characteristic	**360CAS Hip** (Subject device)	**Stryker OrthoMap Versatile Hip System** (Predicate device)
Patient Tracker Fixation	Bone Fixator	OrthoLock with OrthoLock Navigation Pin or OrthoLock EX-Pins

Substantial Equivalence Conclusion

Based on the comparison of intended use and technological characteristics, each of the 360CAS Knee and 360CAS Hip are similar to the predicate device. The hardware and software verification and validation testing demonstrate that the subject devices meet their performance specifications and will perform as intended in the specified use conditions and that any differences between the subject devices and predicate devices do not raise new questions of safety and effectiveness. Therefore, the subject devices, 360CAS Knee and 360CAS Hip, can be found substantially equivalent to the predicate devices, Stryker OrthoMap Precision Knee System and Stryker OrthoMap Precision Hip System.