January 27, 2023

Kico Knee Innovation Company Pty Limited
Danyon Munro
Head of Regulatory Affairs and Quality Assurance
Suite 3, Building 1, 20 Bridge Street, Pymble NSW
Sydney, New South Wales 2073
Australia

Re: K223927
Trade/Device Name: 360CAS Knee, 360CAS Hip
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: December 30, 2022
Received: December 30, 2022

Dear Danyon Munro:

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,

Jesse Muir -S

For: 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223927

Device Name
360CAS Knee and 360CAS Hip

Indications for Use *(Describe)*
The 360CAS is indicated for patients undergoing orthopaedic surgery and where reference to a rigid anatomical structure can be identified.

The 360CAS Knee is indicated for the following surgical procedures:
• Any form of 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:
• Any form of 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.

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

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4. 510(K) SUMMARY - K223927

4.1 INTRODUCTION

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,
- Guidance for Industry and Food and Drug Administration Staff: The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] issued 28-Jul-2014,
- Guidance for Industry and Food and Drug Administration Staff: The Special 510(k) Program issued 13-Sep-2019.
- Guidance for Industry and Food and Drug Administration: Bundling Multiple Devices or Multiple Indications in a Single Submission issued 22-Jun-2007, and
- Guidance for Industry and Food and Drug Administration Staff: Refuse to Accept Policy for 510(k)s issued 13-Sep-2019.

4.2 510(K) SUMMARY

4.2.1 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:	Danyon Munro
	Head of Regulatory Affairs and Head of Quality Assurance
	+61 435 677 481 (phone)
	danyon.munro@360med.care

Date Prepared:	December 30, 2022

4.2.2 Device Details and Substantial Equivalence Claim

Device Common Name:	Orthopedic Stereotaxic Instrument	
Device Trade Name:	360CAS Knee	360CAS Hip
Regulation Number:	21 CFR 882.4560	
Regulation Name:	Stereotaxic Instrument	
Regulatory Class:	II	
Panel	Orthopedic	
Classification Product Code	OLO	
Predicate Devices	360CAS Knee (K213380)	360CAS Hip (K213380)

4.2.3 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 subject's morphology, navigate surgical instruments and implants and assess state of the joint throughout the surgery. The system consists of 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)).

The subject device is predicated on submission (K213380). The modification driving the subject device submission relates to the change of the spatial tracking component sub-system. The previously cleared device incorporated a tracking camera manufactured by Metria Innovation Inc., whereas the subject device will utilise a tracking camera manufactured by Atracsys LLC.

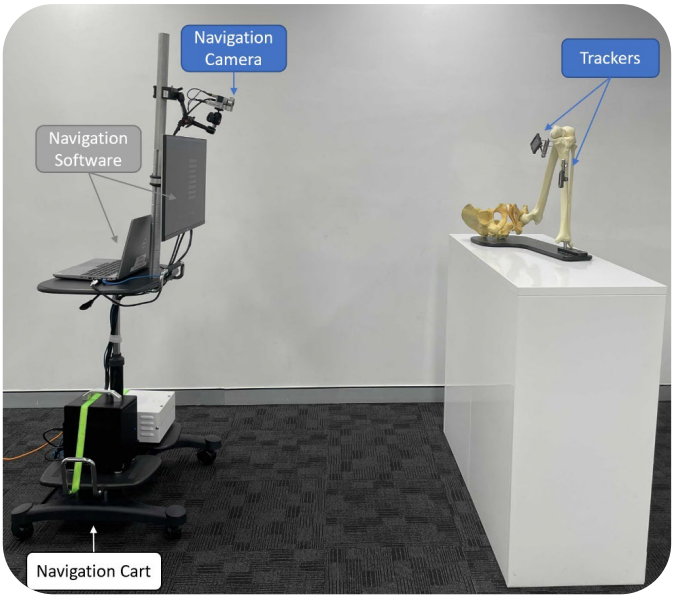

Figure 4-1 - 360CAS Navigation System (Metria)

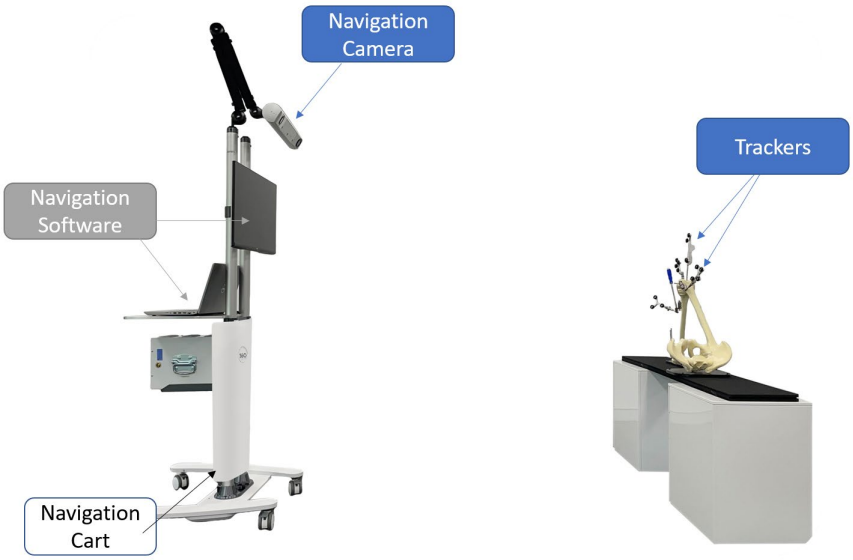

Figure 4-2 - 360CAS Navigation System (Atracsys)

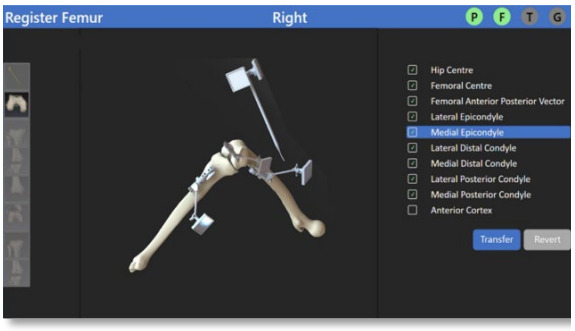

Figure 4-3 - 360CAS Knee Software

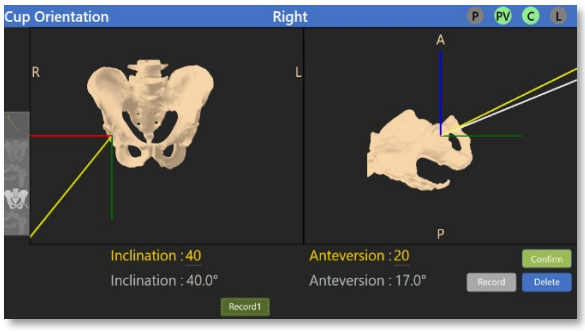

Figure 4-4 – 360CAS Hip Software

4.2.4 Indications for Use for 360CAS

The Indications for Use for 360CAS remains unchanged from the cleared device. It has been included below for clarity.

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.

4.2.5 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:

- 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 summary information 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 and ASTM F2554-22.
- System accuracy testing verifying the specified accuracy of ±2mm and ±1° using Sawbones mimicking patient's anatomy.
- 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.
- 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.

4.2.6 Comparison with the Predicates

Substantial Equivalence Rationale - 360CAS Knee

The 360CAS Knee is considered substantially equivalent to the previously cleared 360CAS Knee regarding clinical, technical, and biological characteristics. The 360CAS Knee and the previously cleared 360CAS Knee 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 previously cleared 360CAS Knee are intended to be used by trained orthopedic 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 previously cleared 360CAS Knee both require AC power to power the computer, monitor and camera. 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 the same software platform developed by Kico Knee Innovation Company Pty Limited. The 360CAS Knee and the previously cleared 360CAS Knee are measuring devices with identical accuracy of ±2 mm and ±1°. Therefore, it is concluded that the 360CAS Knee is substantially equivalent to the previously cleared 360CAS Knee.

Characteristic	**360CAS Knee** (Subject Device)	**360CAS Knee** (Predicate Device)
Trade Name:	Unchanged from previous submission.	360CAS Knee
510(k) Submitter:	Unchanged from previous submission.	Kico Knee Innovation Company Pty Limited

Characteristic	**360CAS Knee** (Subject Device)	**360CAS Knee** (Predicate Device)
510(k) Number:	Under Review	K213380
Regulation Number:	Unchanged from previous submission.	882.4560 – Stereotaxic Instrument
Product Code:	Unchanged from previous submission.	OLO
Product Class:	Unchanged from previous submission.	II
Indications for Use	Unchanged from previous submission.	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 can be identified. The 360CAS Knee is indicated for the following surgical procedures: • Any form of Total Knee Arthroplasty (TKA) • For conditions of the knee joint in which the use of computer assisted surgery may be appropriate
Anatomy	Unchanged from previous submission.	Knee
Patient Population	Unchanged from previous submission.	Patients with medical conditions where use of

Characteristic	360CAS Knee (Subject Device)	360CAS Knee (Predicate Device)
		computer-assisted surgery may be appropriate.
End-Users	Unchanged from previous submission.	Trained orthopaedic surgeon and system operators
Clinical Workflow	Unchanged from previous submission.	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.
Main System Components	Unchanged from previous submission.	Computer Platform Navigation Cart 360CAS Navigation Software - 360CAS Knee Surgical Instruments Spatial Tracking Components
Energy Source	Unchanged from previous submission.	Computer - AC Power
Tracking Technology	Passive Optical tracking technology Retroreflective markers placed in a specified configuration.	Passive optical tracking technology.
Image Display	Unchanged from previous submission.	Monitor
System Accuracy	Unchanged from previous submission.	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 <

Characteristic	**360CAS Knee** (Subject Device)	**360CAS Knee** (Predicate Device)
		±2 mm and a mean rotational error of < ±1°.
Software	Unchanged from previous submission.	360CAS Navigation Software - 360CAS Knee
Patient / Instrument Trackers	Unchanged from previous submission.	<u>Patient/Instrument Trackers</u> • Femur Tracker • Tibia Tracker • Resection Guide Tool <u>Pointer</u> • Pointer
Patient Tracker Fixation	Unchanged from previous submission.	Bone Fixator
Navigated Manual Instruments	• Resection Guide Tool • Cut block	• Resection Guide Tool

Substantial Equivalence Rationale - 360CAS Hip

The 360CAS Hip is considered substantially equivalent to the previously cleared 360CAS Hip regarding clinical, technical and biological characteristics. The 360CAS Hip and the previously cleared 360CAS Hip 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 previously cleared 360CAS Hip 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 the previously cleared 360CAS Hip both require AC power to power the computer, monitor and camera. 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 the same software platform developed by Kico Knee Innovation Company Pty Limited. The 360CAS Hip and the previously cleared 360CAS Hip are measuring devices with accuracy of 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 previously cleared 360CAS Hip.

Characteristic	360CAS Hip (Subject device)	360CAS Hip (Predicate device)
Trade Name:	Unchanged from previous submission.	360CAS Hip
510(k) Submitter:	Unchanged from previous submission.	Kico Knee Innovation Company Pty Limited
510(k) Number:	Under Review	K213380
Regulation Number:	Unchanged from previous submission.	882.4560 – Stereotaxic Instrument
Product Code:	Unchanged from previous submission.	OLO
Product Class:	Unchanged from previous submission.	II
Indications for Use	Unchanged from previous submission.	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

Characteristic	360CAS Hip (Subject device)	360CAS Hip (Predicate device)
		surgery and where reference to a rigid anatomical structure can be identified. The 360CAS Hip is indicated for the following surgical procedures: • Any form of 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 •
Anatomy	Unchanged from previous submission.	Hip
Patient Population	Unchanged from previous submission.	Patients with conditions of the hip-joint where use of computer-assisted surgery may be appropriate.
End-Users	Unchanged from previous submission.	Trained orthopaedic surgeons and system operators
Clinical Workflow	Unchanged from previous submission.	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.
Main System components	Unchanged from previous submission.	Computer Platform Navigation Cart 360CAS Navigation Software

Characteristic	360CAS Hip (Subject device)	360CAS Hip (Predicate device)
		• 360CAS Hip Surgical Instruments Spatial Tracking Components
Energy Source	Unchanged from previous submission.	Computer - AC Power
Tracking Technology	Passive Optical tracking technology Retroreflective markers placed in a specified configuration.	Passive optical tracking technology.
Image Display	Unchanged from previous submission.	Monitor
System Accuracy	Unchanged from previous submission.	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	Unchanged from previous submission.	360CAS Navigation Software • 360CAS Hip
Patient / Instrument Trackers	Unchanged from previous submission.	<u>Patient/Instrument Trackers</u> • Pelvis Tracker • Femur Tracker • Tracker Universal Grip <u>Pointer</u> • Pointer
Patient Tracker **Fixation**	Unchanged from previous submission.	Bone Fixator

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 previous 360CAS Knee and 360CAS Hip predicate devices. 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.