August 8, 2024

Kico Knee Innovation Company Pty Ltd
Danyon Munro
Head of RA, Head of QA
Unit 1, 25 Frenchs Forest Rd E
Frenchs Forest, NSW 2086
Australia

Re: K242009
Trade/Device Name: 360CAS Knee
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: July 10, 2024
Received: July 10, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Tejen D. Soni -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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242009

Device Name

360CAS Knee

Indications for Use *(Describe)*

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

The 360CAS Knee 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

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

1 Applicant Details

Name:	Kico Knee Innovation Company Pty Limited
Address:	Unit 1, 25 Frenchs Forest Road E
	Frenchs Forest, New South Wales 2086
	Australia
Contact Person / Prepared By:	Danyon Munro
	Head of Regulatory Affairs and Head of Quality Assurance
	+61 435 677 481 (phone)
	compliance@360med.care
Date Prepared:	July 10, 2024

2 Device Details and Predicate

Device Common Name:	Orthopedic Stereotaxic Instrument
Device Trade Name:	360CAS Knee
Regulation Number:	21 CFR 882.4560
Regulation Name:	Stereotaxic Instrument
Regulatory Class:	II
Panel:	Orthopedic
Classification Product Code:	OLO
Predicate Devices:	360CAS Knee (K223927)

3 Device Description

The 360 Computer Assisted Surgery (360CAS) is a stereotaxic surgical navigation system designed for orthopedic surgical procedures. The 360CAS device consists of four main components: 360CAS Navigation Software, Surgical Instruments, Spatial Tracking Components, and the Navigation Cart. It is intended to be used as a planning and intraoperative guidance system in open or percutaneous orthopedic surgical procedures. This device utilizes optical tracking technology, enabling surgeons to map patient morphology, navigate surgical instruments, and assess joint conditions throughout the surgery. Optical trackers are attached to navigation instruments, and the Spatial Tracking Components locate the 3D position of these instruments in space. The coordinates are relayed to the 360CAS Navigation Software, which provides the user with relevant orientation and position information. The 360CAS Knee is a specific application of the 360CAS Navigation Software tailored for knee replacement surgery.

4 Intended Use and Indications for Use

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

5 Comparison of Technological Characteristics

The 360CAS System and the predicate 360CAS System, K223927, share the following characteristics:

- Intended use
- Principle of operation
- Spatial tracking system
- Navigation Cart
- Use of surgical instruments
- Computer hardware
- Image display technology
- System accuracy
- Patient anatomy registration and surgical workflow

The subject 360CAS System differs from the predicate device with respect to:

- 360CAS Navigation Software internal architecture
- 360CAS Navigation software development platform

The difference between the subject and the predicate devices concerns the internal workings of 360CAS Navigation software.

They do not raise safety or effectiveness when compared to the predicate device. Both systems achieve the same system accuracy.

6 Performance Data

Design verification and validation testing demonstrated that the 360CAS System meets all design requirements and is as safe and effective as its predicate device (K223927). The following performance tests were performed in support of a substantial equivalence determination:

- Software Verification and Validation Testing as required by IEC 62304
- Positional Accuracy Testing (ASTM F2554)
- Systems accuracy testing
- Non-clinical surgical simulations conducted on bone models

7 Substantial Equivalence

Data presented in this submission demonstrates the 360CAS Knee is substantially equivalent to the previously cleared 360CAS Knee (K223927).

Substantial equivalence has been demonstrated through a comparison of intended use, design and technological characteristics, as well as performance evaluations.