March 21, 2025

Kico Knee Innovation Company Pty Limited
% Stefanie Auf Der Mauer
Regulatory Affairs Consultant
Stefanie Michele Auf der Mauer Asmuss
22 Monfield
Rochestown, Cork T12C65D
Ireland

Re: K243980
Trade/Device Name: ARVIS Surgical Navigation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: SBF
Dated: December 23, 2024
Received: December 23, 2024

Dear Stefanie Auf Der 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 (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Shumaya Ali -S

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.

510(k) Number *(if known)*
K243980

Device Name
ARVIS Surgical Navigation System

Indications for Use *(Describe)*
The ARVIS Surgical Navigation System is indicated for assisting the surgeon in the positioning and alignment of implants relative to reference alignment axes and landmarks in stereotactic orthopedic surgery.
The system aids the surgeon in making intraoperative measurements such as changes in leg length in Hip Arthroplasty.
The system is compatible with straight acetabular impactors and with specific offset impactors, identified in the instructions for use, for which an adapter has been validated.

Example orthopedic surgical procedures include but are not limited to:
• Total Knee Arthroplasty
• Unicompartrnental Knee Arthroplasty: Tibial Transverse Resection
• Hip Arthroplasty

The ARVIS head mounted display is for displaying augmented reality visualization and information to the user intraoperatively. The augmented/ virtual displayed information should not be relied upon solely for absolute positional/alignment information and should always be used in conjunction with the displayed stereotaxic information.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

Prepared: 2025-03-20

1. Submitter Information

Submitter: Kico Knee Innovation Company Pty Ltd
Unit 1, 25 Frenchs Forest Rd E
Frenchs Forest NSW 2086
Australia

Submitter Contact: Matthew Ryan, VP R&D Surgical Automation and Visualization
Email: matthew.ryan@enovis.com
Phone: 949-290-8210

Correspondent: Stefanie Auf der Mauer
Email: stefanie.aufdermauer@enovis.com
Phone: +353 85 759 1774

2. Subject Device

Trade Name: ARVIS® Surgical Navigation System

Regulation: 21 CFR 882.4560 – Stereotaxic Instrument

Classification Name: Orthopedic Augmented Reality

Product Code: SBF

3. Predicate Device

510(k) Number: K203115

Trade Name: ARVIS® Surgical Navigation System

Submitter: Insight Medical Systems, Inc.

Product Code: OLO

4. Device Description Summary

ARVIS® Surgical Navigation System is a computer-controlled surgical navigation system intended to provide intra-operative measurements to the surgeon to aid in selection and positioning of orthopedic implant components.

The subject device is the fundamentally unchanged predicate ARVIS® Surgical Navigation System. It is indicated for use in knee and hip arthroplasties. ARVIS® Surgical Navigation System combines software, electronic hardware and surgical instruments to intraoperatively track tools and locate anatomical structures based on the patient's preoperative imaging.

The navigation platform is identical to the predicate and uses the same electronic hardware, mounted on the surgeon's head and waist.

The subject device adds the capability to remotely activate graphical user interface (GUI) buttons and check boxes for the surgeon, who optionally can use this to work in

conjunction with the current methods of gaze and voice control. The added capability is intended to provide a third alternate option for the surgeon to interact with the software.

ARVIS® Surgical Navigation System displays measurements as described in Performance Claims.

5. Indications for Use

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6. Technological Comparison

The subject device ARVIS® Surgical Navigation System is the same as the predicate ARVIS® Surgical Navigation System in Intended Use, operating principle, main system components, materials, and navigation tracking technology and accuracy.

The technological difference between the subject device and predicate is that the subject device allows input activation of GUI buttons and check boxes from a tablet device. The device changes have been verified and validated with existing well-established methods. The results demonstrate that the subject device is substantially equivalent to the previously cleared ARVIS® Surgical Navigation System (K203115).

7. Non-Clinical Tests Summary and Conclusions

The following performance tests were completed to demonstrate substantial equivalence of safety and effectiveness with the predicate device:

- Software Verification and Validation

Clinical testing was not required to demonstrate substantial equivalence.

The performance data provided in this submission demonstrate that ARVIS® Surgical Navigation System is as safe, effective, and performs as well as the predicate device.