



January 13, 2025

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

Re: K243950
Trade/Device Name: ARVIS® Shoulder
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: SBF, LLZ, QIH
Dated: December 20, 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

Indications for Use

510(k) Number (if known)

K243950

Device Name

ARVIS® Shoulder

Indications for Use (Describe)

ARVIS® Shoulder 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 and locating anatomical structures of the shoulder joint based on the patient's preoperative imaging.

The system is intended to be used with the head mounted ARVIS® Eyepiece display for augmented reality visualization and information, such as visualization of the preoperative plan and display of instrument and implant alignment information. 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.

ARVIS® Shoulder is indicated for total shoulder arthroplasty using the Enovis Altivate, LimaCorporation PRIMA, and LimaCorporation SMR implant systems.

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

Prepared: 2025-01-08

1. Submitter Information

Submitter: Kico Knee Innovation Company Pty Ltd
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2. Subject Device

Trade Name: ARVIS® Shoulder
Regulation: 21 CFR 882.4560 – Stereotaxic Instrument
Classification Name: Orthopedic Augmented Reality
Product Code: SBF, LLZ, QIH

3. Predicate Device

510(k) Number: K240062
Trade Name: ARVIS® Shoulder
Submitter: Insight Medical Systems, Inc.
Product Code: OLO, LLZ, QIH

4. Device Description Summary

ARVIS® Shoulder is a computer-controlled navigation system for shoulder arthroplasty. It aids the surgeon in making intra-operative measurements and locating anatomical structures of the shoulder joint based on the patient's preoperative imaging to assist with selection and positioning of orthopedic implant components. The system consists of software, electronic hardware and surgical instruments.

The ARVIS® Eyepiece is mounted on the surgeon's head and contains tracking cameras that locate the positions of trackers on the patient and instruments. All system measurements, instructions, prompts, and alerts are shown to the surgeon on the Eyepiece display. The Eyepiece communicates with the Belt Pack which is worn by the surgeon around their waist and houses the computer module that runs the ARVIS® Shoulder application software.

The device's workflow involves CT based preoperative planning followed by intraoperative navigation and execution. The preoperative planning software enables 3D virtual implant positioning based on the patient's CT reconstructed digital bone model and bony landmarks. The shoulder navigation application software then matches the patient's digital bone model and landmarks to the intraoperative landmarks registered by the surgeon, allowing an image-based navigation to follow. The surgeon uses the plan data as guidance to navigate and help position shoulder instruments and implants.

The preoperative planning platform uses AI-based automatic image segmentation and landmarking algorithms. The algorithms and the data used to train and test these remain unchanged from the original submission. The data used to train and test the algorithms was labeled and validated in advance by trained experts. The total data consisted of 300 CT scans (from 300 patients) acquired from candidates for shoulder joint replacement surgery. The cohort was partitioned into two disjoint subsets through random sampling, with 80% producing a training dataset and 20% constituting the test dataset. The training dataset consisted of 240 CT scans (from 240 patients). Patient ages ranged from 36 to 89 years (mean age of 70), with 46% male and 54% female. All CT scans were acquired using FDA cleared CT scanners.

5. Indications for Use

ARVIS® Shoulder 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 and locating anatomical structures of the shoulder joint based on the patient's preoperative imaging.

The system is intended to be used with the head mounted ARVIS® Eyepiece display for augmented reality visualization and information, such as visualization of the preoperative plan and display of instrument and implant alignment information. 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.

ARVIS® Shoulder is indicated for total shoulder arthroplasty using the Enovis AltıVate, LimaCorporation PRIMA, and LimaCorporation SMR implant systems.

6. Indications for Use Comparison

The Indications for Use of the predicate device are maintained in the subject device. The subject device expands the implant compatibility to include LimaCorporate shoulder implant systems.

This compatibility difference does not result in a new intended use; the subject device with extended compatibility is intended to be used in the same manner as the predicate device. The difference in the Indications for Use does not affect the safety and effectiveness of the subject device as demonstrated by testing.

In line with the primary product code change, the subject device Indications for Use were updated to include the system's use with the head mounted augmented reality display.

7. Technological Comparison

The subject device ARVIS® Shoulder is the same as the predicate (K240062) in 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 is compatible with additional implant systems. The device compatibility has been verified with existing well-established methods. The results demonstrate that the subject device is substantially equivalent to the previously cleared ARVIS® Shoulder.

8. 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.

Risk analysis and performance data provided in this submission demonstrate that ARVIS® Shoulder is as safe, effective, and performs as well as its predicate device.