



April 29, 2024

Insight Medical Systems, Inc.
% Stefanie Auf Der Mauer
Regulatory Affairs Consultant
Stefanie Michele Auf der Mauer Asmuss (sole trader)
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Rochestown, Cork T12C65D
Ireland

Re: K240062
Trade/Device Name: ARVIS® Shoulder
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: March 29, 2024
Received: March 29, 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.

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

Submission Number (if known)

K240062

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.

ARVIS® Shoulder is indicated for total shoulder arthroplasty using the Enovis Altivante implant system.

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

Prepared: 2024-03-29

1. Submitter Information

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2. Subject Device

Trade Name: ARVIS® Shoulder
Common Name: Orthopedic Stereotaxic Instrument
Regulation: 21 CFR 882.4560 – Stereotaxic Instrument
Product Code: OLO, LLZ, QIH

3. Predicate Device

510(k) Number: K203115
Trade Name: ARVIS® Surgical Navigation System
Manufacturer: Insight Medical Systems, Inc.
Product Code: OLO

4. Reference Devices

510(k) Number: K213546
Trade Name: ExactechGPS Total Shoulder Application, Equinox Planning Software
Manufacturer: Blue Ortho
Product Code: OLO, LLZ

510(k) Number: K222767
Trade Name: PeekMed web
Manufacturer: Peek Health, S.A.
Product Code: QIH, LLZ

5. Device Description Summary

ARVIS® Shoulder 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 equivalent shoulder system of the predicate ARVIS® Surgical Navigation System used for indicated knee and hip arthroplasties. ARVIS® Shoulder 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 uses the same electronic hardware, mounted on the surgeon's head and waist, as the predicate device. A new equivalent navigation application and a new equivalent surgical instrument set are provided to allow surgeons to navigate instruments in shoulder arthroplasty procedures.

The ARVIS® Shoulder workflow involves CT based reconstruction of the patient's shoulder anatomy and preoperative planning to enable image-based navigation. 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 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.

The navigation system is intended to be used with the Enovis AltıVate implant system.

ARVIS® Shoulder displays measurements as described in Performance Claims.

6. 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.

ARVIS® Shoulder is indicated for total shoulder arthroplasty using the Enovis AltıVate implant system.

7. Indications for Use Comparison

The subject device is indicated specifically for total shoulder arthroplasty whereas the predicate device is indicated specifically for knee and hip related arthroplasties. The difference in the Indications for Use does not result in a new intended use; the systems

are both intended to provide intra-operative measurements to the surgeon to aid in selection and positioning of orthopedic implant components. The difference in the Indications for Use does not affect the safety and effectiveness of the subject device as demonstrated by safety and performance testing.

8. Technological Comparison

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

The workflow, patient interface and components used in the subject and predicate device are nearly identical during surgical navigation. The primary technological difference between the subject device and predicate is that the subject device is an image-based system (requiring preoperative imaging and planning for navigation inputs) whereas the predicate device is an imageless system that solely uses intraoperative registrations for development of surgeon guidance. Similar image processing and planning software functions exist in identified reference devices. The additional software functions do not change the Intended Use of the subject device, nor do they raise different questions of safety and effectiveness.

9. Non-Clinical Tests Summary and Conclusions

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

- Positional Accuracy Testing (ASTM F2554)
- Accuracy After Mechanical Disturbances Testing (ASTM F3107)
- Benchtop Accuracy Testing
- Cadaveric Accuracy Testing
- Cadaver Validation
- Software Verification and Validation, including validation of the deep learning algorithms used for automatic image segmentation and landmarking. Details about this performance test are as follows:
 - o Study steps: The reference, ground-truth label for each CT volume in the testing dataset was obtained by a manual process, reviewed, and approved by a trained engineer with more than 2 years' experience with medical image processing and 2 orthopaedic surgeons with subspecialty qualifications in upper limb surgery. The algorithm-generated outputs for every CT scan of the test dataset were compared to the manual ground truth segmentation and landmarking outputs by calculating applicable metrics and assessing against predefined acceptance criteria.
 - o Testing dataset: Validation was performed on a set of 60 CT scans (from 60 patients) acquired from patients who were candidates for shoulder joint replacement surgery. To ensure independence of training and test datasets, the latter was always stored separately and only made available for performance validation.

The testing dataset is composed of 55% female and 45% male patient CT scans. Age ranges from 36 to 86 years, the mean age is 67 years, and the standard deviation is 10.5 years. Ethnicity was not recorded.

The cohort of CT scans were acquired using FDA cleared CT scanners with settings defined in the CT Protocol or comparable. CT scanner manufacturers include Toshiba, Siemens, Philips, GE Medical Systems and Canon.

- o Testing criteria: The difference between the automatic segmentation outputs and manual outputs were quantified using the Dice Similarity Coefficient (DSC), Mean Absolute Distance (MAD) and Hausdorff Distance (HD). The pre-defined acceptance criteria used are specified in the results table below. The difference between the automatic landmarking outputs and the manual outputs were quantified using the Euclidean Distance (ED) and the Angular Separation (AS), and the Successful Point and Angular Classification Rates (SPCR, SACR). The pre-defined acceptance criteria used are specified in the results table below.
- o Testing results: The AI algorithms used for automatic image segmentation and landmarking were able to successfully execute all required steps and met all pre-defined acceptance criteria.

Segmentation Validation Results Summary

	DSC		MAD		HD	
	AC	Result	AC	Result	AC	Result
Scapula	Avg DSC > 0.9	0.981	Avg MAD ≤ 2mm	0.229mm	Avg HD ≤ 5mm	0.824mm
Humerus		0.989		0.352mm		0.917mm

Landmarking Validation Results Summary

	Mean ED / AS		SPCR / SACR	
	AC	Result	AC	Result
Glenoid Center	≤ 3.72mm	1.79mm	≥75%	95.0%
Trigonum		1.86mm		95.0%
Inferior Point		2.11mm		94.9%
Medial Epicondyle		3.19mm		83.3%
Lateral Epicondyle		3.29mm		83.3%
Neck Plane Position		2.01mm		90.0%
Neck Plane Orientation	≤ 10°	8.70°		86.7%

Clinical testing was not required to demonstrate substantial equivalence.

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