July 14, 2021

Insight Medical Systems Inc.
% Bob Duffy
President
Bob Duffy Associates, Inc.
16405 Summer Sage Rd.
Poway, California 92064

Re: K203115
Trade/Device Name: ARVIS® Surgical Navigation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: June 9, 2021
Received: June 11, 2021

Dear Bob Duffy:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203115

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
• Unicompartmental Knee Arthroplasty: Tibial Transverse Resection
• Hip Arthroplasty

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

This 510(k) Summary is being submitted in accordance with the requirements established by 21 CFR 807.92.

1. Submitter Information

Submitter:	Insight Medical Systems, Inc.
Address:	8601 Ranch Road 2222 Building 1, Suite 104 Austin, TX 78730-2304 (USA)
Contact Person:	Nicholas R. van der Walt Chief Executive Officer Phone: (949) 468-7775 Email: nvanderwalt@insightmedsys.com
Date Prepared:	July 14, 2021

2. Subject Device

Trade Name:	ARVIS® Surgical Navigation System
Common Name:	Orthopedic Stereotaxic Instrument
Classification:	21 CFR 882.4560
Classification Name:	Orthopedic Stereotaxic Instrument
Product Code:	OLO
FDA Panel:	84 - Neurology
Class:	II

3. Predicate Device

510(k) Number:	K172462
Manufacturer:	OrthAlign, Inc.
Trade Name:	OrthAlign Plus System
Classification:	21 CFR 882.4560
Classification Name:	Orthopedic Stereotaxic Instrument
Product Code:	OLO
FDA Panel:	84 - Neurology
Class:	II

4. Reference Device

510(k) Number:	K190929
Manufacturer:	Augmedics Ltd.
Trade Name:	Xvision Spine System (XVS)
Classification:	21 CFR 882.4560
Classification Name:	Orthopedic Stereotaxic Instrument
Product Code:	OLO
FDA Panel:	84 - Neurology
Class:	II

5. Device Description

The ARVIS® Surgical Navigation System (ARVIS® System) is to be used by orthopedic surgeons and operating room staff who perform hip and knee arthroplasty.

The ARVIS® System uses cameras to measure locations and angles between trackers mounted on the patient and trackers mounted on surgical instruments. By prompting the user through a procedure-specific workflow to register the reference tracker to anatomic landmarks, the ARVIS® Application Software calculates and displays positions of the instruments relative to the patient's anatomy.

The Eyepiece Assembly contains stereo infrared (IR) tracking cameras, a color camera, a stereo display, IR illumination, and IR laser illuminator. The Eyepiece also includes a headlight. The Eyepiece communicates with the Belt Pack via a cable connection.

The Belt Pack houses the computer module, the battery, and the power management board. The Belt Pack supplies power to the eyepiece and computer module. The computer module runs the ARVIS® Application Software.

All system instructions, prompts, alerts, and outputs are displayed to the surgeon on the Eyepiece display. The ARVIS® System Eyepiece is worn on the surgeon's head via a surgical helmet. The ARVIS® Belt Pack is worn on the surgeon's belt or waistband. No electronic hardware is applied to the patient. The surgeon stands adjacent to the patient to operate. The ARVIS® Battery Charger is intended to be used outside the operating room.

The ARVIS® System comprises the major elements listed in Table 1.

Table 1: ARVIS® Surgical Navigation System Components.

Item	Description	Purpose
1	Eyepiece Assembly	Houses display, speakers, cameras, and other sensors.
2	Belt Pack	System power management. Houses the External Battery and Computer module.
3	Computer Module	Runs the ARVIS® Application Software.
4	External Battery	Removable/swappable. Provides power to the Eyepiece Assembly and the Computer module.

5	Eyepiece Cable	Connects Eyepiece to the Belt Pack.
6	Battery Charging System	Charges External Battery when system is not in use. Intended to be used outside the operating room.
9	Instrument Set	Surgical tools, including trackers, mounts, adapters, etc. that are required to perform surgical procedures.

6. Intended Use

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

The Intended Use of the ARVIS® System is substantially the same as that of the predicate device. Minor differences in wording are not critical to the intended surgical use of the device, and the difference does not affect the safety and effectiveness of the device when used as labeled.

7. Indications for Use

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
- Unicompartmental Knee Arthroplasty: Tibial Transverse Resection
- Hip Arthroplasty

8. Technological Characteristics

Table 2 provides a comparison of the technological characteristics between the ARVIS® System (Subject device) and the OrthAlign Plus System (Predicate device).

Table 2: Comparison of Technological Characteristics.

Characteristic	Subject Device	Predicate Device	Same / Different
Materials	• Metal grades common to orthopedic surgical instruments. • Polymer grades common to orthopedic surgical instruments. • Internal electronics.	• Metal grades common to orthopedic surgical instruments. • Polymer grades common to orthopedic surgical instruments. • Internal electronics.	Same

Characteristic	Subject Device	Predicate Device	Same / Different
Biocompatibility Categorization (ISO 10993-1)	• External Communicating Device, Tissue/Bone/Dentin Communicating, with subsystems that have direct and potential indirect contact for a limited contact duration (< 24 hours).	• External Communicating Device, Tissue/Bone/Dentin Communicating, with subsystems that have direct and potential indirect contact for a limited contact duration (< 24 hours).	Same
Main System Components	• Waist-mounted Belt Pack with non-sterile, reusable mobile computer module and system Battery. • Optical and inertial sensors, illumination, and display in non-sterile, reusable Head-mounted Eyepiece. • Reusable sterile mechanical instrument set.	• Sterile single-use computer module with internal, non-replaceable Battery. • Inertial sensors and display in sterile, single-use module. • Reusable electronic sensor with Battery. • Reusable sterile mechanical instrument set.	Different
Operating Principle	• Computer processor uses positional information from tracked markers on anatomy or instruments to calculate and display measurements to the user.	• Computer processor uses positional information from sensors on anatomy or instruments to calculate and display measurements to the user.	Same
Tracking Technology	• Optical – stereo infrared cameras. • Inertial – for head tracking and measurements relative to gravity.	• Inertial – accelerometer and gyroscope. • Optical – monocular camera (for hip registration probe scale reader).	Different
Registration	• Instruments placed at indicated anatomic points. • System's optical and inertial sensors used to determine position and/or orientation of instruments or anatomy to which trackers or sensors are attached.	• Instruments placed at indicated anatomic points. • System's optical and inertial sensors used to determine position and/or orientation of instruments or anatomy to which trackers or sensors are attached.	Same

Characteristic	Subject Device	Predicate Device	Same / Different
User Interface	• Text and graphical output on LCD in Eyepiece. • Audible feedback Eyepiece-mounted internal speakers. • Eyepiece-mounted microphone. • Head tracking interface and voice commands to control and navigate the application software.	• Text and graphical output on LCD in single-use computer module. • Audible feedback from speakers in single-use computer module. • Physical buttons on sterile single-use module to control and navigate the application software.	Different
Patient Interface	• Tracking markers and cutting guides pinned to bone. • Landmarks registered with mechanical probe tip. • No electronics applied to patient.	• Inertial sensors and cutting guides pinned to bone. • Landmarks registered with mechanical probe tip. • Battery-powered sensors mounted on patient.	Different
Sterilization - reusable mechanical instruments	• Steam sterilization for reusable mechanical instruments.	• Steam sterilization for reusable mechanical instruments.	Same
Sterilization – Electronic components	• No sterilization required for electronic components.	• EtO sterilization for single-use computer module.	Different
Energy Type	• Electronics: Battery Power. • Instruments: Mechanical (Manual).	• Electronics: Battery Power. • Instruments: Mechanical (Manual).	Same
Environmental Specifications	• Temperature: -30 to 50 °C. • Humidity: 10 to 90% RH; (non-condensing). • Pressure: 60 kPa to 106 kPa.	Specified storage and operating environments for typical transport and surgical environments.	Same

As shown in Table 2, the following technological characteristics are the same for the ARVIS® System and the OrthAlign Plus System:

a. Materials
b. Biocompatibility Classification per ISO 10993-1
c. Operating Principle
d. Registration
e. Environmental Specifications

As also shown in Table 2, the following technological characteristics are different between the ARVIS® System and the OrthAlign Plus System:

1. Main System Components
2. Tracking Technology
3. User Interface
4. Patient Interface
5. Sterilization

Using a combination of Risk Management, design specifications and implementation, and verification and validation, these differences are not critical to the intended surgical use of the device, and do not affect the safety and effectiveness of the device when used as labeled.

The Augmedics Xvision is named as a Reference Device because it includes the technological characteristic of a heads-up display similar to that in the subject device.

9. Non-Clinical Performance Data

9.1. Summary of Non-Clinical Testing Performed and Conclusions Drawn

A program of non-clinical verification and validation testing was conducted that includes:

- Cleaning process Validation
- Sterilization Validation
- Software Verification and Validation Testing
- Electromagnetic Compatibility (EMC) testing
- Electrical Safety testing
- Safety and Performance Bench Testing
- Simulated Clinical Validation Testing

Cleaning process Validation was performed to validate that the ARVIS® Instruments can be adequately cleaned using the specified procedure provided in the Instructions for Use.

Sterilization Validation was conducted to demonstrate that:

a. The ARVIS® Surgical Instruments are compatible with the necessary FDA-cleared reprocessing equipment,
b. The reprocessing instructions are technically feasible for implementation by users, and
c. The sterilization process has been validated to attain a sterility assurance level (SAL) of 10^{-6}.

Software Verification and Validation Testing was conducted to demonstrate that:

1) All requirements and specifications in the ARVIS® Software Requirements Specification were implemented and operate correctly.
2) All Risk Mitigations to be implemented in software were implemented and operated correctly, and
3) the software conforms with the user needs and intended uses of the ARVIS® device.

Electromagnetic Compatibility (EMC) testing was conducted to demonstrate that the ARVIS® System is compliant with applicable Standards for Electromagnetic Compatibility.

Electrical Safety testing was conducted to demonstrate that the ARVIS® System is compliant with applicable Standards for Electrical Safety.

Safety and Performance Bench Testing was conducted to demonstrate that the ARVIS® System meets its performance specifications and is substantially equivalent to the predicate device performance.

Simulated Clinical Validation Testing was conducted to demonstrate that the particular requirements for the specified intended use can be consistently fulfilled by the ARVIS® System. This testing was conducted in a human cadaveric setting and included validation of user requirements and navigation accuracy.

9.2. Clinical Testing

No clinical testing was conducted for a determination of substantial equivalence.

10. Overall Conclusion

The documentation and test results provided in this submission and comparison of intended use, principle of operation, performance data, design and the overall technological characteristics, demonstrate that the ARVIS® Surgical Navigation System is as safe, as effective, and performs as well as the predicate device.