Intellijoint Surgical Inc.
Breanne Cuddington
Regulatory Affairs Associate
60 Bathurst Drive
Unit 6
Waterloo, N2V 2A9 CA

October 1, 2019

Re: K191507
Trade/Device Name: Intellijoint® Navigation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: August 30, 2019
Received: September 3, 2019

Dear Breanne Cuddington:

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)*
K191507

Device Name
Intellijoint® Navigation System

Indications for Use *(Describe)*
The Intellijoint® Navigation System is a computer-controlled, optical localizer intended to provide intra-operative measurements to a surgeon to aid in selection and positioning of orthopedic implant system components, where a reference to a rigid anatomical structure can be identified. The Intellijoint Navigation System is indicated for patients undergoing orthopedic surgery, and where the use of stereotactic surgery is considered safe and effective.

Intellijoint HIP aids the surgeon in performing intra-operative measurements including measurements of limb position, joint center-of-rotation, and implant component positioning.

Intellijoint KNEE aids the surgeon in performing intra-operative measurements including alignment of instrumentation and bony cuts for implant component positioning.

Example orthopedic surgical procedures include, but are not limited to:
- Total Hip Arthroplasty
- Minimally Invasive Hip Arthroplasty
- Revision Hip Arthroplasty
- Total Knee 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.

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510(k) Summary

1. Submitter Information

Submitter: **Intellijoint Surgical Inc.**
Address: 809 Wellington St. N, Unit 2
Kitchener, ON
Canada N2H 5L6

Telephone: (519) 342–3178
Fax: (226) 317–0471

Contact: Breanne Cuddington

Date Prepared: 30 August 2019

2. Device Information

Trade Name: Intellijoint® Navigation System
Common Name: Orthopedic Stereotaxic Instrument
Classification: Class II per 21 CFR 882.4560
Classification Name: Orthopedic Stereotaxic Instrument
Product Code: OLO

3. Purpose of Submission

The purpose of this submission is to gain clearance for updates to the indications for use for the Intellijoint HIP Generation 2B System, which has been previously cleared in K171525. The updated product will be referred to as the Intellijoint® Navigation System throughout the submission.

4. Predicate Device Information

The Intellijoint® Navigation System described in this submission is substantially equivalent to the following predicate devices:

Primary Predicate:

Device Name	Manufacturer	510(k) No.
KneeAlign 2 System	OrthAlign, Inc.	K103829

Additional Predicate:

Device Name	Manufacturer	510(k) No.
Intellijoint HIP Generation 2B System	Intellijoint Surgical Inc.	K171525

5. Device Description

The Intellijoint® Navigation System (IJNS) is an imageless optical navigation system intended for use in orthopedic surgery. The IJNS consists of an infrared Camera, Camera Drape, optical tracking Spheres, a computer Workstation and associated hardware.

This submission provides the addition of Total Knee Arthroplasty (TKA) to the indications for use (cleared in K171525), allowing real-time measurements of varus/valgus angle, flexion/extension angle, and resection depth for distal femur and proximal tibia cuts during TKA procedures. The modifications include the addition of TKA-specific mechanical instruments and software. The updated product will be referred to as the Intellijoint® Navigation System throughout this submission.

6. Indications for Use

The Intellijoint® Navigation System is a computer-controlled, optical localizer intended to provide intra-operative measurements to a surgeon to aid in selection and positioning of orthopedic implant system components, where a reference to a rigid anatomical structure can be identified. The Intellijoint® Navigation System is indicated for patients undergoing orthopedic surgery, and where the use of stereotactic surgery is considered safe and effective.

Intellijoint HIP® aids the surgeon in performing intra-operative measurements including measurements of limb position, joint center-of-rotation, and implant component positioning.

Intellijoint KNEE™ aids the surgeon in performing intra-operative measurements including alignment of instrumentation and bony cuts for implant component positioning.

Example orthopedic surgical procedures include, but are not limited to:

- Total Hip Arthroplasty
- Minimally Invasive Hip Arthroplasty
- Revision Hip Arthroplasty
- Total Knee Arthroplasty

7. Comparison of Technological Characteristics

The substantial equivalence of the Intellijoint® Navigation System compared to the predicate devices is based on the following technological characteristics:

Property	**Intellijoint® Navigation System**	**Primary Predicate**	**Additional Predicate**
		KneeAlign® 2 System	Intellijoint HIP® Generation 2B System
510(k) No.	K191507	K103829	K171525
Tracking method	Optical	Inertial	Optical
Imaging Modality	Imageless	Imageless	Imageless
Camera System	Monocular	N/A	Monocular
Registration Method	**HIP** Same as K171525	**HIP** N/A	**HIP** i. Camera rigidly fixed to pelvis. ii. Digitization of Anterior Pelvic Plane and/or frontal / sagittal planes.

Property	Intellijoint® Navigation System	Primary Predicate	Additional Predicate
		KneeAlign® 2 System	Intellijoint HIP® Generation 2B System
	KNEE i. Bone Tracker mounted rigidly to Femur or Tibia ii. Digitization of Femoral or Tibial Landmarks	**KNEE** i. Navigation unit mounted rigidly to Femur or Tibia ii. Digitization of Femoral or Tibial landmarks	**KNEE** N/A

8. Performance Data

This submission provides the addition of TKA to the indications for use cleared in 510(k) K171525 and adds the Intellijoint KNEE™ Software Application to the Intellijoint® Navigation System. Other modifications include the addition of TKA specific mechanical instruments to the Intellijoint® Navigation System.

The following tests were performed to support the addition of Intellijoint KNEE™ and to demonstrate the substantial equivalence of the Intellijoint® Navigation System to its predicate devices:

Test	Summary	Result
Verification		
Benchtop Accuracy	Verified clinical accuracy requirements using calibrated benchtop test fixtures.	All accuracy requirements were met.
Tracking System Accuracy and Robustness	Accuracy of Intellijoint KNEE was verified according to the methodology in ASTM F2554-10 – Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems. Testing simulated normal conditions, and a variety of worst-case use scenarios and realistic tracking disturbances.	All accuracy specifications and robustness requirements were met.
Software Functional and Unit Tests	Verified that the Intellijoint KNEE Software Application satisfies functional requirements and performs as intended. Algorithms and measurement calculations were also verified in these tests.	Software satisfied all requirements and specifications.
Mechanical Instrumentation Functional and Performance Tests	Provides confirmation that mechanical instrumentation satisfies functional and performance requirements.	All functional and performance requirements met.

Validation		
Anatomical Phantom Simulated Use and Clinical Accuracy	Simulated use testing was performed on bone models by orthopedic surgeons in a simulated TKA procedure following a typical workflow. This test validated that Intellijoint KNEE satisfies user needs, intended use and clinical accuracy requirements. Accuracy was assessed by comparing simulated use measurements with ground truth values.	All user needs and clinical accuracy requirements were met.
Cadaver Simulated Use	Simulated use testing was also performed in cadaver labs. These tests validated that Intellijoint KNEE satisfies clinical use requirements and performs as intended when: - Operated by a surgeon - Used on human specimens - Used in a realistic operating room environment	All clinical use requirements were met.

The testing demonstrated that the Intellijoint® Navigation System is substantially equivalent to the legally marketed predicate devices for its intended use.

9. Conclusion

Based on the indications for use, technological characteristics, performance testing, and comparison to the predicate devices, the Intellijoint® Navigation System has been shown to be substantially equivalent to the legally marketed predicate devices identified in this submission and does not present any changes to safety or effectiveness.