Intellijoint Surgical Inc.
Brandon Gingrich
Quality and Regulatory Affairs Manager
60 Bathurst Drive, Unit 6
Waterloo, Ontario N2V 2A9
Canada

October 30, 2017

Re: K171525
Trade/Device Name: Intellijoint HIP Generation 2B System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: October 5, 2017
Received: October 6, 2017

Dear Brandon Gingrich:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)* K171525

Device Name
Intellijoint HIP Generation 2B System

Indications for Use *(Describe)*

The Intellijoint HIP Generation 2B 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 HIP Generation 2B System is indicated for patients undergoing orthopedic surgery, and where the use of stereotactic surgery is considered safe and effective. The system aids the surgeon in performing intra-operative measurements including measurements of limb position, joint center-of-rotation, and implant component positioning. Example orthopedic surgical procedures include, but are not limited to:

- Total Hip Arthroplasty
- Minimally Invasive Hip Arthroplasty
- Revision 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.

510(k) Summary

1. Submitter Information

Submitter: **Intellijoint Surgical Inc.**
Address: 60 Bathurst Dr., Unit 6
Waterloo, ON
Canada N2V 2A9

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

Contact: Brandon Gingrich

Date Prepared: May 23, 2017

2. Device Information

Trade Name: Intellijoint HIP® Generation 2B 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 a previously cleared Computer-Assisted Orthopedic Surgery System.

4. Predicate Device Information

The Intellijoint HIP® Generation 2B System described in this submission is substantially equivalent to the following predicates:

Predicate Device	Manufacturer	510(k) No.
Intellijoint HIP® Generation 2A System	Intellijoint Surgical Inc.	K162364
Stryker OrthoMap Versatile Hip System	Stryker Leibinger GmbH	K162937

5. Device Description

The Intellijoint HIP® Generation 2B System is an imageless optical navigation system intended for use in orthopedic surgery. The device provides intra-operative assessment of patient leg length, offset, anterior-posterior change, hip center of rotation change, and acetabular cup angle during Total Hip Arthroplasty procedures. The system is composed of an infrared Camera, Tracker, computer workstation, software, and bone fixation instruments/hardware.

The Intellijoint HIP® Generation 2B System is an update to the Intellijoint HIP® System previously cleared in 510(k) K162364. This submission provides the addition of revision hip arthroplasty (RHA) procedures to the indications for use, and the use of either linear

or non-linear acetabular cup impactors. Other minor modifications made to the device are also provided.

6. Intended Use

The Intellijoint HIP Generation 2B 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 HIP Generation 2B System is indicated for patients undergoing orthopedic surgery, and where the use of stereotactic surgery is considered safe and effective. The system aids the surgeon in performing intra-operative measurements including measurements of limb position, joint center-of-rotation, and implant component positioning.

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

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

7. Comparison of Technological Characteristics

The substantial equivalence of the Intellijoint HIP® Generation 2B System to the predicates is shown by similarity in intended use, indications for use, and performance.

8. Performance Data

This submission is for updates to the Intellijoint HIP® Generation 2A System cleared in 510(k) K162364. The following tests were performed to demonstrate the substantial equivalence of the updated Intellijoint HIP® Generation 2B 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.
Software Functional and Unit Tests	Verified that the 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.
Bone Fixation Functional and Performance Tests	Provides confirmation that new hardware (Femoral Disc and Femoral Disc Rod) satisfy 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 THA procedure following a typical workflow. This test validated that the Intellijoint HIP® Generation 2B System 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 a cadaver lab. This test validated that the Intellijoint HIP® Generation 2B System 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 HIP® Generation 2B 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 HIP® Generation 2B 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.