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

November 16, 2017

Re: K172849
Trade/Device Name: Intellijoint HIP System (Cart), Intellijoint HIP System (Portable), Intellijoint HIP Instrument Tray
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: October 31, 2017
Received: November 1, 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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)*

K172849

Device Name
Intellijoint HIP Generation 2C System

Indications for Use *(Describe)*

The Intellijoint HIP Generation 2C 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 system is only compatible with straight acetabular cup impactors.

The Intellijoint HIP Generation 2C 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

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

K172849

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: September 19, 2017

2. Device Information

Trade Name: Intellijoint HIP® Generation 2C 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 sterilization and packaging processes as included in a previously cleared Computer-Assisted Orthopedic Surgery System.

4. Predicate Device Information

510(k) No.	Device	Manufacturer
K151364 Concurrence: 28-Dec-2015	Intellijoint HIP® Generation 2 System	Intellijoint Surgical Inc.
K162364 Concurrence: 2-Mar-2017	Intellijoint HIP® Generation 2A System	Intellijoint Surgical Inc.

5. Device Description

The Intellijoint HIP® Generation 2C 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.

This submission describes updates implemented to provide terminally sterile bone screws to the user, which were previously only supplied non-sterile. The intended use and fundamental scientific technology is unchanged, and remains substantially equivalent to the predicate device.

6. Intended Use

Intellijoint HIP Generation 2C 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 system is only compatible with straight acetabular cup impactors.

Intellijoint HIP Generation 2C 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

7. Comparison of Technological Characteristics

This modification does not alter the device's fundamental scientific technology in comparison to the predicate devices (K151364 and K162364) and therefore has the same technological characteristics.

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 system to its predicates.

Test	Brief Description	Result
Manufacturing Cleaning Process	Verified the cleaning process used during the manufacture of the Intellijoint HIP Pelvic and Femur Screws.	All gravimetric residue acceptance criteria were met.
Biocompatibility Analysis	Cytotoxicity analysis was used to evaluate the cytotoxicity level of samples following manufacturing, cleaning, and sterilization.	All acceptance criteria met with no deviations.
Packaging Integrity Testing	Physical and Climatic stress testing of packaging system, including visual integrity, seal integrity and strength testing.	All packaging system design and integrity requirements were met.
Sterilization Validation Testing	Substantiated gamma irradiation sterilization dose for the terminal sterilization of the Intellijoint HIP Pelvic and Femur Screws.	All sterility requirements were met.

Sterile Barrier System Integrity Tests	Sterile barrier system integrity evaluated by visual inspection of seals and pouches for anomalies. Seal width measurements, bubble leak test, and seal strength were also evaluated.	All acceptance criteria were met with no deviations.
Shelf-life/Aging Tests	Real-time 5-year sterile barrier system integrity of the QSEAL® Tyvek pouch assessed by contract packager. Accelerated aging studies were used to assess the performance of the clear barrier film (48GA PET/28lb LDPE) and Tyvek® 1073B used in the IJH2C System sterile Screw pouches.	No degradation to sterile barrier system over a five-year period.
Pyrogenicity Testing	Limulus amebocyte lysate (LAL) testing was performed to quantify bacterial endotoxin levels and confirm endotoxin limits are met.	Bacterial endotoxin limits were met.

9. Conclusion

The changes proposed in this submission do not alter the intended use, operating principle, and technological characteristics in comparison to the approved legally marketed predicate devices (K151364 and K162364). The design development processes of the Intellijoint HIP® System conforms to currently valid standards, including applicable medical device safety and performance standards. The modifications proposed do not affect the safety and effectiveness of the device.