DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 28, 2015

Intellijoint Surgical, Incorporated
Mr. Brandon Gingrich
Quality and Regulatory Affairs Manager
60 Bathurst Drive, Unit 1
Waterloo, Ontario
Canada N2V 2A9

Re: K151364
Trade/Device Name: Intellijoint HIP™ System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: November 16, 2015
Received: November 17, 2015

Dear Mr. 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 Parts 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 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 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 yours,

Ronald P. Jean -S for

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)*
K151364

Device Name
Intellijoint HIP™ SYSTEM

Indications for Use *(Describe)*
Intellijoint HIP is a computer-controlled, optical localizer intended to provide intra-operative measurements to a surgeon to aid in selection and positioning of orthopaedic 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 is indicated for patients undergoing orthopaedic 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 orthopaedic 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.

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510(k) Summary

1. Submitter Information

Submitter:	**Intellijoint Surgical Inc.**
Address:	60 Bathurst Dr., Unit 1 Waterloo, ON Canada N2V 2A9
Telephone:	(519) 342 – 3178
Fax:	(226) 317 – 0471
Contact:	Brandon Gingrich
Date Prepared:	December 28th, 2015

2. Device Information

Trade Name:	**Intelli**joint **HIP™** System
Common Name:	Orthopaedic Stereotaxic Instrument
Classification:	Class II per 21 CFR 882.4560
Classification Name:	Orthopaedic Stereotaxic Instrument
Product Code:	OLO

3. Purpose of Submission

The purpose of this submission is to gain clearance for updates to a previously cleared Computer-Assisted Orthopaedic Surgery System.

4. Predicate Device Information

The **intelli**joint **HIP™** System described in this submission is substantially equivalent to the following predicates:

Predicate Device	Manufacturer	510(k) No.
intellijoint **HIP™** System	Intellijoint Surgical, Inc.	K133759
Navitrack™ System – Total Hip Replacement CT-Free	ORTHOsoft, Inc.	K041369

5. Device Description

The **intelli**joint **HIP™** System is an imageless optical navigation system intended for use in orthopaedic 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 (THA) procedures. The system is composed of an infrared Camera, Tracker, computer workstation, software, and bone fixation instruments/hardware.

This submission is an update to the **intelli**joint **HIP™** System previously cleared in 510(k) K133759. The updates include an acetabular cup alignment feature, modifications to the method of patient registration, and other minor design and aesthetic improvements.

6. Intended Use

Intellijoint HIP™ is a computer-controlled, optical localizer intended to provide intra-operative measurements to a surgeon to aid in selection and positioning of orthopaedic 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™ is indicated for patients undergoing orthopaedic 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 orthopaedic surgical procedures include, but are not limited to:

- Total Hip Arthroplasty
- Minimally Invasive Hip Arthroplasty

7. Comparison of Technological Characteristics

The substantial equivalence of the **intelli**joint **HIP™** System to the predicates is shown by similarity in intended use, indications for use, materials, and performance.

8. Performance Data

The following tests were performed to demonstrate the substantial equivalence of the **intelli**joint **HIP™** System to its predicate devices:

Verification		
Test	**Brief Summary**	**Result**
Tracking System Accuracy and Robustness	The **intelli**joint **HIP™** System's accuracy 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.
Benchtop Accuracy	Verified clinical accuracy requirements using calibrated benchtop test fixtures.	All accuracy requirements were met.
Bone Fixation Performance	Verified bone fixation performance requirements including functional tests, robustness, rigidity of fixation and repeatability.	All functional and performance 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.

Electrical Safety and EMC	Compliance with ANSI / AAMI / IEC 60601-1:2005 for medical electrical equipment: - Part 1: General requirements for basic safety and essential performance - Part 1-2: Collateral standard— Electromagnetic compatibility – requirements and tests - Part 1-6: Collateral Standard: Usability	Compliance with the requirements of the standards demonstrated.
Biocompatibility Evaluation	Evaluation against the applicable requirements of ISO 10993-1:2009 – Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process - Part 5: Tests for in vitro cytotoxicity - Part 10: Tests for irritation and skin sensitization - Part 11: Tests for systemic toxicity	Compliance with the requirements of the standards demonstrated.
Validation		
Test	**Brief Summary**	**Result**
Anatomical Phantom Simulated Use and Clinical Accuracy	Simulated use testing was performed on bone models by orthopaedic surgeons in a simulated THA procedure following a typical workflow. This test validated that the **intelli**joint **HIP™** 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 **intelli**joint **HIP™** System satisfies clinical use requirements and performs as intended when: - Operated by a surgeon - Used on human specimens - Used in a realistic OR environment	All clinical use requirements were met.

The testing demonstrated that the **intelli**joint **HIP™** System is substantially equivalent to the legally marketed predicate devices for its intended use in facilitating the accurate positioning of orthopaedic implants where a reference to rigid anatomical structures can be identified relative to the anatomy.

9. Conclusion

Based on the indications for use, technological characteristics, performance testing, and comparison to the predicate devices, the **intelli**joint **HIP™** System has been shown to be substantially equivalent to the legally marketed predicate devices identified in this submission, and does not present any new issues of safety or effectiveness.