SECTION 5 – 510(k) Summary

510(k) Summary
Intellijoint HIP™ System

1. Submitter Information

Submitter:	Intellijoint Surgical Inc.
Address:	60 Bathurst Dr., Unit 1 Waterloo, ON Canada N2V 2A9
Telephone:	519.342.3178
Contact:	Brandon Gingrich
Date Prepared:	July 21st, 2014

2. Device Information

Trade Name:	Intellijoint HIP™ 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 a new Computer-Assisted Orthopedic Surgery System.

4. Predicate Device Information

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

Predicate Device	Manufacturer	510(k) No.
DASH Hip System	BrainLAB AG	K110021
StealthStation Imageless Hip Module	Medtronic	K052623

5. Device Description

The Intellijoint HIP™ System is an imageless optical navigation system intended for orthopedic surgery. The Intellijoint HIP™ System provides intra-operative assessment of patient leg length and offset during Total Hip Arthroplasty (THA) procedures. The system is composed of an infrared sensor, a tracked reflective

marker assembly (beacon), a computer workstation, software, and bone fixation components. The infrared sensor is affixed to the patient's pelvis and the beacon is attached to the patient's femur. The system records the position and orientation of the femur relative to the pelvis prior to hip dislocations. This baseline information can then be used to track the change in leg length and leg offset during the joint replacement procedure.

6. Intended Use

Intellijoint HIP™ is an infrared, computer-controlled localizer intended to provide intra-operative measurements to a surgeon to aid in selection and positioning of orthopedic implant system components, relative to anatomical structures and reference axes.

Intellijoint HIP™ is indicated for patients undergoing orthopedic surgery where the use of stereotactic surgery is considered safe and effective, and where a reference to a rigid anatomical structure, such as a long bone, can be identified relative to the anatomy. The system aids the surgeon in controlling leg length and offset discrepancies.

Example orthopedic 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 Intellijoint 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 Intellijoint HIP™ System to its predicate devices:

Test	Brief Summary	Result
Verification		
Tracking System Accuracy	The Intellijoint HIP™ System's accuracy was verified using the Intellijoint HIP™ software application according to the methodology in ASTM F2554-10 – Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems.	All accuracy specifications were met.
Benchtop Accuracy and Robustness	Verified clinical accuracy requirements using calibrated benchtop test fixtures while simulating normal use, a variety of worse-case use scenarios and realistic tracking disturbances.	All accuracy and robustness 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 verified in these tests.	Software satisfied all requirements and specifications.
Electrical Safety and EMC	Compliance with ANSI/AAMI ES60601-1:2005/(R)2012 for medical electrical equipment: - Part 1: General requirements for basic safety an d essential performance - Part 1-2: General requirements for basic safety and essential performance – collateral standard—Electromagnetic compatibility – requirements and tests	Compliance with the requirements of the standards demonstrated.

Biocompatibility Evaluation	Evaluation against the applicable requirements of ANSI/AAMI/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		
Sawbones Simulated Use and Accuracy	Non-clinical simulated use testing was performed on bone models (sawbones) by orthopedic surgeons in a simulated THA procedure following a typical THA workflow. This test validated that the Intellijoint 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 and Accuracy	Pre-clinical simulated use testing was performed in a cadaver lab. This test validated that the Intellijoint HIP™ system satisfies clinical use/accuracy requirements and performs as intended when: - Operated by a surgeon - Used on human specimens - Used in a realistic OR environment	All clinical use and accuracy requirements were met.

The testing demonstrated that the Intellijoint HIP™ System is substantially equivalent to the legally marketed predicate devices for its intended use in facilitating the accurate positioning of orthopedic 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 Intellijoint 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 29, 2014

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

Re: K133759
Trade/Device Name: Intellijoint HIP™
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Product Code: OLO
Regulatory Class: Class II
Dated: June 25, 2014
Received: June 26, 2014

Dear Mr. Gingrich:

This letter corrects our substantially equivalent letter of July 23, 2014.

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 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,

Lori A. Wiggins

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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K133759

Device Name
Intellijoint HIP™

Indications for Use *(Describe)*
Intellijoint HIP™ is an infrared, computer-controlled localizer intended to provide intra-operative measurements to a surgeon to aid in selection and positioning of orthopedic implant system components, relative to anatomical structures and reference axes.

Intellijoint HIP™ is indicated for patients undergoing orthopedic surgery where the use of stereotactic surgery is considered safe and effective, and where a reference to a rigid anatomical structure, such as a long bone, can be identified relative to the anatomy. The system aids the surgeon in controlling leg length and offset discrepancies.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices