



Food and Drug Administration  
10903 New Hampshire Avenue  
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ZIMMER CAS

September 11, 2014

Mr. Christopher Mclean  
Quality and regulatory Affairs Associate Director  
75 QUEEN STREET, SUITE 3300  
MONTREAL, Canada H3C 2N6

Re: K141601

Trade/Device Name: iASSIST™ Knee System  
Regulation Number: 21 CFR 882.4560  
Regulation Name: Stereotaxic instrument  
Regulatory Class: Class II  
Product Code: OLO  
Dated: August 11, 2014  
Received: August 12, 2014

Dear Mr. Mclean:

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" (21CFR 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,

**Mark N. Melkerson -S**

Mark N. Melkerson  
Director  
Division of Orthopedic Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K141601

Device Name

iASSIST Knee System

Indications for Use (Describe)

The iASSIST Knee System is a computer assisted stereotaxic surgical instrument system to assist the surgeon in the positioning of orthopedic implant system components intra-operatively. It involves surgical instruments and position sensors to determine alignment axes in relation to anatomical landmarks and to precisely position alignment instruments and implant components relative to these axes.

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

**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)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K141601

**510(K) SUMMARY OF SAFETY AND EFFECTIVENESS**  
**iASSIST™ KNEE SYSTEM**

**Applicant:** Zimmer CAS  
75 Queen Street, suite 3300  
Montreal, Quebec  
Canada, H3C 2N6  
Tel.: 514 861 4074  
Fax: 514 866 2197

**Contact Person:** Christopher McLean

**Date Summary Prepared:** June 12, 2014

**Device Trade Name:** iASSIST™ Knee System

**Device Classification Name:** Orthopedic Stereotaxic Instrument (product code OLO); 21 CFR § 882.4560

**Predicate Device:**

iASSIST Knee System, from Zimmer CAS, 510(k) # K122326, cleared Nov. 30<sup>th</sup>, 2012

**Device Description:**

As in the predicate, the iASSIST Knee System consists of tracking sensors ('pods'), a computer system, software, and surgical instruments designed to assist the surgeon in the placement of Total Knee Replacement components. The pods combined with the surgical instruments provide positional information to help orient and locate the main femoral and tibial cutting planes as required in knee replacement surgery. This includes means for the surgeon to determine and thereafter track each of the bones' alignment axes relative to which the cutting planes are set.

**Indications for Use / Intended Use:**

This is unchanged from the predicate:

The iASSIST Knee System is a computer assisted stereotaxic surgical instrument system to assist the surgeon in the positioning of orthopedic implant system components intra-operatively. It involves surgical instruments and position sensors to determine alignment axes in relation to anatomical landmarks and to precisely position alignment instruments and implant components relative to these axes.

Example orthopedic surgical procedures include but are not limited to: Total Knee Arthroplasty.

**Technological Comparisons to the Predicates:**

The fundamental scientific technology of the predicate is unchanged including the operating principle and control mechanism.

The changes involved altering the system to allow for an alternate surgical flow requiring only 2 pods as compared to the predicate 4 pod method. This involved the introduction of a new 2 pod kit along with software adjustments to allow for the altered step sequence.

In addition, general system improvements and updates have been implemented in the predicate. These involved secondary engineering changes and improvements. They did not involve

changes to the intended and indication for use and did not raise any new issues of safety and effectiveness. These included the following:

- Update of the pod electrical certification to latest IEC 60601-1:2005 electrical safety standard
- Removal of no longer used or redundant pod and instrument graphical symbols and mechanical interfaces
- The modification or addition instruments and methods to facilitate use and improve the compatibility with implant systems
- Improvements to the system software components to improve system usability, to increase the robustness of bone registration and wireless communication algorithms, to further increase the resistance to electro-static discharges, and to further ensure the pod's battery lifetime to accommodate the system changes.

**Performance Data:**

Non-clinical tests were performed to assess that no new safety and efficacy issues were raised in the device. The main tests included the following:

1. Software system tests were performed to ensure that the required functionalities were maintained or correctly updated per the changes without the introduction of hazardous anomalies. They included the hardware and user interfaces, the communication protocols, the use of pods and instruments as applicable, the response to temperature effects, and the verification of fault conditions.
2. Performance tests were performed under simulated bench test conditions and analyses to verify the implementation of the performance of the bone registration related functionalities.
3. Bench test and analyses were performed to verify the robustness and compatibility of the added or modified instruments, to verify the resistance of the pods to electro-static discharges, and to verify the sufficiency the pod's battery expected lifetime as in the predicate.
4. Full use simulations tests using sawbones were performed to verify and validate the overall system performance in terms of the system usage, surgical flow, and instrument ergonomics.
5. Electrical certification test related to the certification update.

**Conclusion:**

The information and data provided in this 510(k) Premarket Notification established that the modified iASSIST Knee System is substantially equivalent to its predicate version.