K122326 NOV 30 2012

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

Applicant: Zimmer CAS
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Canada, H3C 2N6
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Contact Person: Christopher McLean

Date Summary Prepared: November 9, 2012

Device Trade Name: iASSIST™ Knee System

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

Predicate Device:
KneeAlign 2 System, form OrthAlign Inc., 510(k) # K103829

Device Description:
The iASSIST Knee System consists of tracking sensors, a computer system, software, and surgical instruments designed to assist the surgeon in the placement of Total Knee Replacement components.
The tracking sensors 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. The computer system and software components control and sequence the functions of the sensors per the applicable knee surgery steps via wireless communication.

Indications for Use / Intended Use:
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 main technology in the iASSIST Knee system is the same as in the predicate. In both cases accelerometer and gyroscope based (inertial) sensors are assembled or combined with manual surgical instruments to provide navigation information for the manual placement of orthopedic implants intra-operatively, with the operation and functions of the sensors being computer controlled. Both systems involve providing the same navigation information for the same femoral and tibial cutting planes for knee replacement surgery. Other implementation methods are similar between both systems

- similar software algorithm and hardware to sequence and control the sensors and user interface functions via wireless communication,
- similar software and instrument features to determine and track the alignment axes to reference the cutting planes,
- similar instrument features and functions to allow assembly of the sensors, to attach the subject bones, to register or digitize the applicable landmarks, and to adjust the alignment of provided saw guides,

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. Biocompatibility tests were performed on the tracking sensor devices to ensure that the use of membrane switch interfaces with encapsulated LEDS does not involve any bio-incompatible effects. These involved cytotoxicity (MEM Elution), irritation (Intracutaneous Sensitivity), and systemic toxicity (Maximization Sensitization) tests in accordance with ISO 10993-1 for either Externally Communicating or Implant type device with tissue/bone contact up to 24 hours. Materials with established biocompatibility characteristics were used in the reminder of the patient contact instruments.
2. Software System tests were performed to ensure that no hazardous anomalies were present in the system software components. They consisted of testing software features and functionalities in correspondence to software design requirements. They included the hardware interfaces, the use of the tracking sensor and instruments as applicable, the verification of fault conditions, and installation tests.
3. Performance tests were performed under simulated bench test conditions to verify the implementation of the software algorithms and the system accuracy for each accuracy related function: calibration, femur registration, tibia registration, tibia navigation, femur navigation, and tibia & femur cut validation.
4. Full use simulations tests using cadaver specimens or sawbones were performed by multiple surgeons to verify and validate the overall system performance in terms of system usage and instrument ergonomics. The results demonstrated satisfactory performance per the intended use including obtaining overall Hip-Knee-Ankle alignments within ±3° of target in 90% of the cases per design requirements.
5. Electrical, electromagnetic compatibility, and wireless telecommunication tests were performed to demonstrate compliance to IEC 60601-1, IEC 60601-1-2, and FCC 47 CFR part 15.
6. Sterilization and packaging validation tests as applicable for the Tracking Sensors which are provided sterile using Ethylene Oxide were performed in compliance with ISO 11135 and ISO 11607 respectively to ensure and maintain an SAL of 10^{-6} over the over the shelf life of the product.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Zimmer
% Mr. Christopher McLean
Quality and Regulatory Affairs Associate Director
75 Queen Street, Suite 3300
Montreal, Canada H3C 2N6

November 30, 2012

Re: K122326
Trade/Device Name: iAssist™ Knee System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: November 09, 2012
Received: November 13, 2012

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Peter D. Rumm -S

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

Enclosure

510(k) Number: K122326

Device Name: iASSIST™ Knee System

Indications for Use:

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

Prescription Use ✓ OR Over-the-Counter Use _____
(per 21CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R.P. Ogden 2012.11.30 10:44:16 -05'00'

(Division Sign-Off)
Division of Surgical Devices
510(k) Number _____