510(K) SUMMARY OF SAFETY AND EFFECTIVENESS
CAS PSI KNEE SYSTEM

Applicant: Zimmer CAS
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SEP 1 3 2013

Contact Person: Christopher McLean

Date Summary Prepared: August 15, 2013

Device Trade Name: CAS PSI Knee System

Device Name / Product Code, Regulation Classification Name / Number:
1) Knee Arthroplasty Implantation System / OOG, Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis / 21 CFR § 888.3560
2) Prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer / JWH, Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis / 21 CFR § 888.3560
3) Prosthesis, Knee, Patello/Femorotibial, Semi-Constrained, Uncemented, Porous, Coated, Polymer/Metal / MBH, Knee Joint Patellofemorotibial Metal/Polymer Porous-Coated Uncemented Prosthesis / 21 CFR § 888.3565

Predicate Devices:

1. Zimmer Patient Specific Instruments System 5.0, Submitter: Materialise N.V., K121640
2. Zimmer Patient Specific Instruments System 2.5, Submitter: Materialise N.V., K111492

Device Description:
The CAS PSI Knee is an orthopedic instrument system indicated to assist in the positioning of knee replacement components. It involves surgical planning software used pre-operatively, and surgical instrument components that include patient specific guides to precisely align and position the implant components intra-operatively relative to each patient's anatomical features per the surgical plan. The surgical planning software allows the review of patient joint models determined from radiological images upon which the surgical placement of the implant components is adjusted per anatomical landmarks. The patient specific guides are fabricated per the patient models to fit each patient's anatomy with features that set the relative placement of the implant components per the surgical plan. The system is compatible with given implant systems per its indications for use.

Indications for Use / Intended Use:
The CAS PSI Knee System is indicated as an orthopedic instrument system to assist in the positioning of knee replacement components. It involves surgical planning software used pre-operatively to plan the surgical placement of the components on the basis of provided patient radiological images with identifiable placement anatomical landmarks, and surgical instrument components that include patient specific or customized guides fabricated on the basis of the surgical plan to precisely reference the placement of the implant components intra-operatively per the surgical plan.
The CAS PSI Knee System is to be used with the following fixed bearing knee replacement systems in accordance with their indications and contraindications: NexGen CR, NexGen CR-Flex, Nexgen CR-Flex Gender, Nexgen LPS, Nexgen LPS-Flex, Nexgen LPS-Flex Gender, Persona CR, and Persona PS.
The patient specific guide components are intended for single-use only.

Technological Comparisons to the Predicates:
The main technology in the CAS PSI Knee system is the same as in the predicates. Both the CAS PSI Knee system and the predicates involve an equivalent software package to pre-operatively model the patients anatomy from MRI scans, identify surgical landmark on the patient models in accordance with the implant surgical technique to reference the placement of the implants, plan the placement of the implants upon the model and per the surgical landmarks, and to create corresponding models for Femoral and Tibial Guides with surfaces and elements to uniquely fit each patient topographical features and set or reference the placement of the implant system components per the plan.
While the Femoral and Tibial Guides provide the same functions in both the CAS PSI Knee system and the predicates, in the CAS PSI Knee system the tibial guide functions are provided by two guides as compared to one single guide in the predicates. The predicate Tibial Guide combines features to set both the location of the implant tibial cut guides as well as the location of the implant tibial component on the cut surface. In the CAS PSI Knee this is provided by one guide to set the location of the implant system's tibial cut guide, and a separate Tibial Rotational Guide to locate the implant's tibial component on the cut surface. While provided separately the approach is equivalent since the intended use to place the implant component is the same.
Another difference is that the system includes additional instrument accessories called Drop Rod Adaptors. These allow for the intra-operatively validation of the alignment provided by the Tibial Guide while the Tibial Guide is still set on the patient. In the predicates the user is similarly instructed to perform the verification of the alignment of the tibial cut with, however, the difference that it is done only once the cut guide is positioned on the patient after the predicate Tibial Guides have been removed, and also that it is by using the implant's system drop rod adaptors instruments as intended for this purpose. While the approach is different, the intended use to verify the alignment imparted by the Tibial Guides is equivalent.
A final difference is that the CAS PSI Knee system includes full scale 3-D reproductions of the bone models of each patient's distal femur and proximal tibia on which the locations of the guides and reference landmarks are depicted per the surgical planning. These allow the surgeon to visually gage intra-operatively the accuracy of the bone

models relative to the actual patient's anatomy and the relative placement of the guides per the plan. Given their intent to provide more information for the user to gage the accuracy of the planning and guides, these do not raise new safety or effectiveness concerns.

Performance Data:

Four different types of non-clinical tests to were conducted to verify and validate the performance of the system and assess that no new safety and efficacy issues were raised in the device.

- **Software System Tests**: They 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.
- **Software Performance Tests:** Tests were performed to verify the reproducibility and accuracy of the software system algorithms. These included the accuracy and reproducibility of the software tools, the model meshing and segmentation methods, the assignment of surgical landmarks, the planning method, and the jig creation algorithms.
- **Guide Mechanical Resistance Tests:** Tests were performed to verify the mechanical performance of the guides including resistance to use or drop breakage, debris generation, aging stability, sterilization, and extreme shipping conditions.
- **Full System Validation Tests:** 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.

Conclusion:

The information and data provided in the 510(k) Premarket Notification established that the CAS PSI Knee System is substantially equivalent to the predicates.

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

Zimmer CAS
Mr. Christopher McLean
Quality & Regulatory Affairs Associate Director
75 Queen Street, Suite 3300
Montreal, Quebec H3C 2N6
CANADA

September 13, 2013

Re: K131409
Trade/Device Name: CAS PSI Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.
Regulatory Class: Class II
Product Code: JWH, MBH, OOG
Dated: August 15, 2013
Received: August 16, 2013

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 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. 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,

Mark N. Melkerson -S

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

Enclosure

510(k) Number: K131409

Device Name: CAS PSI Knee System

Indications for Use:

The CAS PSI Knee System is indicated as an orthopedic instrument system to assist in the positioning of knee replacement components. It involves surgical planning software used pre-operatively to plan the surgical placement of the components on the basis of provided patient radiological images with identifiable placement anatomical landmarks, and surgical instrument components that include patient specific or customized guides fabricated on the basis of the surgical plan to precisely reference the placement of the implant components intra-operatively per the surgical plan.

The CAS PSI Knee System is to be used with the following fixed bearing knee replacement systems in accordance with their indications and contraindications: NexGen CR, NexGen CR-Flex, Nexgen CR-Flex Gender, Nexgen LPS, Nexgen LPS-Flex, Nexgen LPS-Flex Gender, Persona CR, and Persona PS.

The patient specific guide components are intended for single-use only.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices