K122033 (1/6)

SEP 27 2012

5.0 510(K) SUMMARY:

Submitter's Name and Address	ConforMIS Inc. 11 North Ave. Burlington, MA 01803
Establishment Registration Number	3004153240 and 3008690421
Date of Summary	June 9, 2012
Contact Person	Amita S. Shah, Vice President, Quality Assurance and Regulatory Affairs
Telephone Number	(781) 345-9164
Fax Number	(781) 345-0104
Name of the Device	ConforMIS iTotal® CR Knee Replacement System (KRS)
Common or Usual Name	Cruciate Retaining Total Knee Replacement System
Classification Name	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulation Number	21 CFR 888.3560
Device Classification	Product Code: JWH, Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis. OOG, Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis. Intended to be used to assist in the implantation of a specific knee arthroplasty device or a set of specific knee arthroplasty devices. Indicated to include guiding alignment, making or establishing cuts, selecting, sizing, attaching, positioning or orienting implant components.

Indications for Use

The iTotal® CR Knee Replacement System is intended for use as a total knee replacement in patients with knee joint pain and disability whose conditions cannot be solely addressed by the use of a prosthetic device that treats only one or two of the three knee compartments, such as a unicondylar, patello-femoral or bi-compartmental prosthesis.
The Indications for Use include:

- Painful joint disease due to osteoarthritis, traumatic arthritis, rheumatoid arthritis or osteonecrosis of the knee.
- Post traumatic loss of joint function.
- Moderate varus, valgus or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Failed osteotomies, hemiarthoplasties, and unicondylar, patello-femoral or bi-compartmental implants.

The implant is intended for cemented use only

Identification of the Legally Marketed Device (Predicate Device)

ConforMIS iTotal CR Knee Replacement System (KRS)

Device Class:	II
Product Code:	JWH, OOG
Regulation Number:	21 CFR 888.3560
510(k) number:	K094050, K103117, K112780, K113378, K120068, K120316

Device Description

The iTotal Cruciate Retaining Knee Replacement System (hereafter referred to as the "iTotal CR KRS") is a patient-specific tricompartmental faceted posterior cruciate ligament (PCL) retaining knee replacement system. The iTotal CR KRS is a semi-constrained cemented knee implant which consists of a femoral, tibial and patellar component. The product design incorporates a bone preserving approach with minimal bone resection of the tibia and femur for the treatment of severe pain and/or disability of a knee damaged by osteoarthritis or trauma.

Using patient imaging (either CT or MR scans) and a combination of proprietary and off the shelf software, a patient-specific implant and related instrumentation are designed that best meet the geometric and anatomic requirements of the specific patient. The femoral component is manufactured from cobalt chromium molybdenum ("CoCrMo") alloy. The tibial component includes a metal tray manufactured from CoCrMo alloy and either one or two polyethylene inserts manufactured from UHMWPE of identical configuration. The patellar component is manufactured from UHMWPE.

For user convenience, and similar to the predicate iTotal CR KRS, accessory orthopedic manual surgical instruments designed for use with the modified iTotal CR KRS are provided to assist with implantation. The ancillary instruments are provided sterile and for single-use only. These patient-specific instruments are provided to assist in the positioning of total knee replacement components intra-operatively and in guiding the marking of bone before cutting.

The function and general design features of the patient-specific ancillary instruments remain similar to those described in the predicate 510k i.e. K094050, K103117, K112780, K120068, K113378 and K120316.

Substantial Equivalence:

The product subject of this premarket notification is substantially equivalent to the iTotal Cruciate Retaining Knee Replacement System (**K094050** cleared September 16, 2010, **K103117** cleared January 7, 2011, **K112780** cleared December 15, 2011, **K120068** cleared February 3, 2012, **K113378** cleared February 15, 2012 and **K120316** cleared April 19, 2012) The following testing was performed to establish substantial equivalence:

- Software verification and validation testing of proprietary software iTotal iView

Device Comparison

Characteristic	Modified iTotal CR KRS (This submission)	Predicate iTotal CR KRS (K112780 and K120316)
Indication for Use	The iTotal® CR Knee Replacement System is intended for use as a total knee replacement in patients with knee joint pain and disability whose conditions cannot be solely addressed by the use of a prosthetic device that treats only one or two of the three knee compartments, such as a unicondylar, patello-femoral or bi-compartmental prosthesis. The indications for use include: • Painful joint disease due to osteoarthritis, traumatic arthritis, rheumatoid arthritis or osteonecrosis of the knee. • Post traumatic loss of joint function. • Moderate varus, valgus or flexion deformity in which the ligamentous structures can be returned to adequate function and stability. • Failed osteotomies, hemiarthoplasties, and unicondylar, patello-femoral or bi-compartmental implants. The implant is intended for cemented use only	The iTotal® CR Knee Replacement System is intended for use as a total knee replacement in patients with knee joint pain and disability whose conditions cannot be solely addressed by the use of a prosthetic device that treats only one or two of the three knee compartments, such as a unicondylar, patello-femoral or bi-compartmental prosthesis. The indications for use include: • Painful joint disease due to osteoarthritis, traumatic arthritis, rheumatoid arthritis or osteonecrosis of the knee. • Post traumatic loss of joint function. • Moderate varus, valgus or flexion deformity in which the ligamentous structures can be returned to adequate function and stability. • Failed osteotomies, hemiarthoplasties, and unicondylar, patello-femoral or bi-compartmental implants. The implant is intended for cemented use only
Intended for Cement Use Only	Yes	Yes
Product Classification	21 CFR 888.3560 (JWH)	21 CFR 888.3560 (JWH)
Components	• Femoral Component • Metal Backed Tibial Component • Patellar Component	• Femoral Component • Metal Backed Tibial Component • Patellar Component
Materials	• Femoral Implant- CoCrMo • Metal-Backed Tibial Components: o Tibial tray- CoCrMo o Tibial Insert-UHMWPE • Patellar Component: UHMWPE	• Femoral Implant- CoCrMo • Metal-Backed Tibial Components: o Tibial tray- CoCrMo o Tibial Insert-UHMWPE • Patellar Component: UHMWPE

510(k) Summary continued
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Characteristic	Modified iTotal CR KRS (This submission)	Predicate iTotal CR KRS (K112780 and K120316)
Design	Knee joint patellofemorotibial semi – constrained cemented prosthesis	Knee joint patellofemorotibial semi – constrained cemented prosthesis
Configuration-Femoral Implant	• Constant coronal curvature • Patient-specific sagittal J- curves	• Constant coronal curvature • Patient-specific sagittal J- curves
Tibial Implant	• Configuration: Metal Backed Tibial Implant • Single or Dual inserts • Insert sizes:6-16mm • Articulating Surface: curved • Profile: patient-specific • Tray interlock: o Interference fit o Anterior lip o Tray undercut design	• Configuration: Metal Backed Tibial Implant • Single or Dual inserts • Insert sizes:6-16mm • Articulating Surface: curved • Profile: patient-specific • Tray interlock: o Interference fit o Anterior lip o Tray undercut design
Patellar Implant	Symmetrical, offered in sizes ranging from 32, 35, 38, 41 and 44 mm, with corresponding heights of 6, 7, 8.5, 10 and 12mm.	Symmetrical, offered in sizes ranging from 32, 35, 38, 41 and 44 mm, with corresponding heights of 6, 7, 8.5, 10 and 12mm.
Instrumentation	Patient-specific Nylon jigs	Patient-specific Nylon jigs
Principle of Operation	Cemented use Fixed Bearing Design	Cemented use Fixed Bearing Design
Posterior Cruciate Ligament (PCL) Sparing	Yes	Yes
Patient-Matched	Yes	Yes
Packaging	Device components are individually double pouched using Tyvek® /film pouches which are sealed and labeled	Device components are individually double pouched using Tyvek® /film pouches which are sealed and labeled
Patient-specific surgical plan	Generated by iTotal iView software or manually generated	Manually generated
Sterility Method/ Assurance Level	VHP Gas Plasma $1x10^{-6}$	VHP Gas Plasma $1x10^{-6}$
Initial Shelf-Life	6 months	6 months
Labeled Non-pyrogenic	No	No

Description and Conclusion of Testing	**Nonclinical Testing:** The determination of substantial equivalence for this device was based on a detailed device description. The following non-clinical laboratory testing was performed demonstrating that the device is safe and can be considered substantially equivalent to the predicate device for the intended use: • Detailed software description and software verification and validation testing of proprietary software
Safety and Performance	The determination of substantial equivalence for this device was based on a detailed device description. Non-clinical laboratory testing was performed demonstrating that the device is safe and can be considered substantially equivalent to the predicate device for the intended use. Clinical data is not necessary to demonstrate substantial equivalence.
Conclusion:	Based on the testing conducted, it is concluded that the iTotal Cruciate Retaining Knee Replacement System with the use of the iTotal iView production software is substantially equivalent to the iTotal Cruciate Retaining Knee Replacement System (**K094050** cleared September 16, 2010, **K103117** cleared January 7, 2011, **K112780** cleared Dec 15, 2011, **K120068** cleared on February 3, 2012 and **K113378** cleared on February 15, 2012 and **K120316** cleared April 19, 2012.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

SEP 27 2012

Conformis, Incorporated
% Ms. Amita S. Shah
Vice President, Quality Assurance and Regulatory Affairs
11 North Ave
Burlington, Massachusetts 01803

Re: K122033
Trade/Device Name: ConforMIS® iTotal Cruciate Knee Replacement System (iTotal CR KRS)
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, OOG
Dated: July 9, 2012
Received: July 16, 2012

Dear Ms. Shah:

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,

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

Enclosure

Indications for Use

510(k) Number (if known): K122033

Device Name:
ConforMIS® iTotal Cruciate Retaining (CR) Knee Replacement System (iTotal CR KRS)

Indications for Use:
The iTotal® CR Knee Replacement System is intended for use as a total knee replacement in patients with knee joint pain and disability whose conditions cannot be solely addressed by the use of a prosthetic device that treats only one or two of the three knee compartments, such as a unicondylar, patello-femoral or bi-compartmental prosthesis.

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- Failed osteotomies, hemiarthoplasties, and unicondylar, patello-femoral or bi-compartmental implants.

The implant is intended for cemented use only.

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K122033

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)