APR 19 2012



## 510(K) SUMMARY

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| **Submitter's Name and Address** | ConforMIS Inc.<br>11 North Ave.<br>Burlington, MA 01803 |
| **Establishment Registration Number** | 3004153240 |
| **Date of Summary** | January 30, 2012 |
| **Contact Person** | Amita S. Shah, Vice President, Quality Assurance & Regulatory Affairs |
| **Telephone Number** | (781) 345-9164 |
| **Fax Number** | (781) 345-0104 |
| **Name of the Device** | ConforMIS iTotal® CR Knee Replacement System (iTotal CR 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**<br>**Device Classification** | 21 CFR 888.3560<br>Product Code:<br>JWH, Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.<br><br>OOG, Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.<br>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. |

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**510(k) Summary continued**

**Indications for Use**

The iTotal® CR Knee Replacement System (iTotal CR KRS) 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 iTotal CR KRS is intended for cemented use only.

**Identification of the Legally Marketed Device (Predicate Device)**

ConforMIS iTotal CR Knee Replacement System (ITOTAL CR KRS)

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

**Device Description**

The iTotal CR 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 is designed, that best meets 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 two polyethylene inserts manufactured

from UHMWPE. 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 and K112780.

**Substantial Equivalence:**

The product subject of this premarket notification is substantially equivalent to the iTotal Cruciate Retaining Knee Replacement System (K094050 cleared September16, 2010, K103117 cleared January 7, 2011 and K112780 cleared December15, 2011) and other currently marketed, cemented total knee replacement systems. The following testing was performed to establish substantial equivalence:

- Tibial interlock assembly and disassembly testing
- Design validation via cadaveric testing

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**510(k) Summary continued**

**Device Comparison**

| | Predicate iTotal CR Knee Replacement System (K103117) | Modified Device iTotal CR Knee Replacement System (This submission) |
|---|---|---|
| **Components** | • Femoral Component<br>• Tibial Implant<br>Metal Backed Tibial Component<br>• Patellar component | • Femoral Component<br>• Tibial Implant<br>Metal Backed<br>Tibial Component<br>• Patellar component |
| **Materials** | • Femoral Implant: CoCrMo<br>• Metal Backed Tibial Components:<br>o Tibial tray: CoCrMo<br>o Tibial Inserts: UHMWPE<br>• All Polymer Patellar Component: UHMWPE | • Femoral Implant: CoCrMo<br>• Metal Backed Tibial Components:<br>o Tibial tray: CoCrMo<br>o Tibial Inserts: UHMWPE<br>• All Polymer Patellar Component: UHMWPE |
| **Design** | Knee joint patellofemorotibial semi-constrained cemented prosthesis | Knee joint patellofemorotibial semi-constrained cemented prosthesis |
| **Principle of Operation** | Cemented Use fixed Bearing Design | Cemented Use fixed Bearing Design |
| **Patient Matched** | Yes | Yes |
| **Patellar Design/ Dimensions** | Symmetrical, offered in various sizes | Symmetrical, offered in various sizes |
| **Tibial Implant interlock design** | • Interference fit<br>• Anterior lip<br>• Tray undercut design | • Interference fit<br>• Anterior lip<br>• Double Undercut with Central Spine |
| **Minimum Thickness of Tibial Insert (UHMWPE)** | 6 mm | 6 mm |
| **Posterior Cruciate Ligament (PCL) Sparing** | Yes | Yes |
| **Instrumentation** | Patient specific Nylon jigs | Patient specific Nylon jigs |

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**510(k) Summary continued**

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| **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:<br>• Tibial tray/insert interlock assembly/disassembly testing<br>• Cadaveric testing |
| **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 proposed intended use. Clinical data is not necessary to demonstrate substantial equivalence. |
| **Conclusion:** | Based on the testing conducted it is concluded that the modified device is substantially equivalent to the iTotal Cruciate Retaining Knee Replacement System, K094050 cleared September 16, 2010, K103117 cleared January 7, 2011 and K112780 cleared December15, 2011. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

ConforMIS, Incorporated
% Ms. Amita S. Shah
11 North Avenue
Burlington, Massachusetts 01803

APR 19 2012

Re: K120316
Trade/Device Name: iTotal CR Knee Replacement 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, OOG
Dated: January 30, 2012
Received: February 01, 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): K120316

Device Name: iTotal CR Knee Replacement System

Indications for Use:

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

The iTotal CR KRS is intended for cemented use only.

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

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K120316