

FEB - 3 2012

5.0 510(K) SUMMARY

Submitter's Name and Address	ConforMIS Inc. 11 North Ave. Burlington, MA 01803
Establishment Registration Number	3004153240
Date of Summary	January 4, 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
Indications for Use	<p>The iTotal® CR Knee Replacement System (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 :</p> <ul style="list-style-type: none"> • 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, hemiarthroplasties, and unicondylar, patello-femoral or bi-compartmental implants. <p>The iTotal CR KRS is intended for cemented use only.</p>
Identification of the Legally Marketed Device (Predicate Device)	<p>ConforMIS iTotal CR Knee Replacement System (KRS)</p> <p>Device Class: II</p> <p>Product Code: JWH, OOG</p> <p>Regulation Number: 21 CFR 888.3560</p> <p>510(k) number: K094050, K103117 and K112780</p>

510(k) Summary continued**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 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 and K112780.

**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). The following testing was performed to establish substantial equivalence:

- Software verification and validation testing of proprietary software

510(k) Summary continued

Device Comparison

	Predicate iTotal CR Knee Replacement System (K112780)	Modified Device iTotal CR Knee Replacement System (This submission)
Components	<ul style="list-style-type: none"> • Femoral Component • Tibial Implant Metal Backed Tibial Component • Patellar component 	<ul style="list-style-type: none"> • Femoral Component • Tibial Implant Metal Backed Tibial Component • Patellar component
Materials	<ul style="list-style-type: none"> • Femoral Implant: CoCrMo • Metal Backed Tibial Components: <ul style="list-style-type: none"> ○ Tibial tray: CoCrMo ○ Tibial Inserts: UHMWPE • All Polymer Patellar Component: UHMWPE 	<ul style="list-style-type: none"> • Femoral Implant: CoCrMo • Metal Backed Tibial Components: <ul style="list-style-type: none"> ○ Tibial tray: CoCrMo ○ Tibial Inserts: UHMWPE • 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
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
Proprietary Software for femoral iJig instrumentation	N/A –manual process	iTotal FemJigs version 1.0

510(k) Summary continued

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 iTotat Cruciate Retaining Knee Replacement System with the use of the iTotat FemJigs manufacturing software is substantially equivalent to the iTotat Cruciate Retaining Knee Replacement System (K094050 cleared September 16, 2010, K103117 cleared January 7, 2011 and K112780 cleared Dec 15, 2011).

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,



for 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): K120068

Device Name: iTTotal CR Knee Replacement System

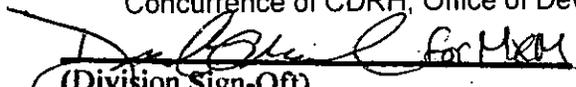
Indications for Use:

The iTTotal® CR Knee Replacement System (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, hemiarthroplasties, and unicondylar, patello-femoral or bi-compartmental implants.

The iTTotal CR KRS is intended for cemented use only.

Prescription Use X AND/OR Over-The-Counter Use
 (Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
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Concurrence of CDRH, Office of Device Evaluation (ODE)

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