K122991

5.0 510(K) SUMMARY (PAGE 1 OF 5)

DEC 2 0 2012

Submitter's Name and Address:	ConforMIS Inc. 11 North Avenue Burlington, MA 01803
Establishment Registration Number:	3004153240
Date of Summary:	September 24, 2012
Contact Person: **Telephone Number:** **Fax Number:**	Amita S. Shah, Vice President, Regulatory and Quality Affairs (781) 345-9164 (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:	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, patellofemoral or bicompartmental 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, patellofemoral or bicompartmental 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, and K120316

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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 of the cutting of bone.

The function and general design features of the patient-specific ancillary instruments remain similar to those described in the predicate 510k notifications i.e. K094050, K103117, K112780, K113378, K120068, 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 07, 2011, **K112780** cleared December 15, 2011, **K113378** cleared February 15, 2012, **K120068** cleared February 03, 2012, and **K120316** cleared April 19, 2012). The following testing was performed to establish substantial equivalence:

- Software verification and validation testing of proprietary software

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Device Comparison

Characteristic	Predicate iTotal CR Knee Replacement System (K112780 & K120316)	Modified Device iTotal CR Knee Replacement System (This submission)
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, patellofemoral or bicompartmental 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, patellofemoral or bicompartmental implants. The iTotal KRS 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, patellofemoral or bicompartmental 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, patellofemoral or bicompartmental 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

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Characteristic	Predicate iTotal CR Knee Replacement System (K112780 & K120316)	Modified Device iTotal CR Knee Replacement System (This submission)
Materials	• Femoral Implant: CoCrMo • Metal Backed Tibial Components: o Tibial tray: CoCrMo o Tibial Inserts: UHMWPE • All Polymer Patellar Component: UHMWPE	• Femoral Implant: CoCrMo • Metal Backed Tibial Components: o Tibial tray: CoCrMo o 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
Posterior Cruciate Ligament (PCL) Sparing	Yes	Yes
Instrumentation	Patient-specific Nylon jigs	Patient-specific Nylon jigs
Proprietary Software for Femoral Components	iTotalWorks version 3.0	iTotalWorks version 4.0
Proprietary Software for Tibial Components	N/A – manual process	iTotalTib version 1.0 or manual process

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Description 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 iTotalWorks • Detailed software description and software verification and validation testing of proprietary software iTotalTib
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 iTotalWorks v4.0 and iTotalTib v1.0 production software is substantially equivalent to the iTotal Cruciate Retaining Knee Replacement System (**K094050** cleared September 16, 2010, **K103117** cleared January 07, 2011 and **K112780** cleared Dec 15, 2011, **K113378** cleared February 15, 2012, **K120068** cleared February 03, 2012, and **K120316** cleared April 19, 2012)

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

Letter dated: December 20, 2012

ConforMIS, Incorporated
% Ms. Amita S. Shah
Vice President, Regulatory and Quality Affairs
11 North Avenue
Burlington, Massachusetts 01803

Re: K122991
Trade/Device Name: ConforMIS® iTotal Cruciate Retaining (CR) 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: September 24, 2012
Received: September 26, 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

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

Enclosure

Indications for Use

510(k) Number (if known): K122991

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, patellofemoral or bicompartmental 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, patellofemoral or bicompartmental implants.

The implant 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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Krishna Asundi

Division of Orthopedic Devices