K122870

510(K) SUMMARY

JAN 1 4 2013

Submitter's Name and Address	ConforMIS Inc. 11 North Ave. Burlington, MA 01803
Establishment Registration Number	3004153240
Date of Summary	December 27, 2012
Contact Person **Telephone Number** **Fax Number**	Amita S. Shah, Vice President, Quality & Regulatory Affairs (781) 345-9164 (781) 345-0104
Name of the Device	ConforMIS iTotal® Cruciate Retaining Knee Replacement System with iPoly XE™ Tibial Inserts and patellae
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. OIY, Prosthesis, knee, patellofemorotibial, semi-constrained, cemented polymer + additive/metal/polymer + additive. This generic type of device includes prosthesis that have a femoral component mode of alloys, such as cobalt-chromium-molybdenum, and a tibial component(s) and/or a retropatellar resurfacing component made of ultra-high molecular weight polyethylene plus an additive, such as a-tocopherol. 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.

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510(k) Summary
continued

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
- Revision procedures provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

The implant is intended for cemented use only

Identification of the Legally Marketed Devices (Predicate Devices)

ConforMIS iTotal CR Knee Replacement System (KRS)
Device Class: II
Product Code: JWH, OOG
Regulation Number: 21 CFR 888.3560
510(k) number: K120316, K120068, K113378, K112780, K103117, K094050

Biomet E-Poly™ Tibial Bearings
Device Class: II
Product Code: JWH, MBH, MBV, OIY
Regulation Number: 21 CFR 888.3560
510(k) number: K080528

DJO Surgical Highly Cross-Linked Vitamin E UHMWPE Tibial Insert and Patella
Device Class: II
Product Code: JWH, MBH, OIY

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Regulation Number: 21 CFR 888.3560
510(k) number: K113756, K103223, K091956

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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.

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 that are manufactured from UHMWPE. The patellar component is also manufactured from UHMWPE.

ConforMIS is proposing a line extension of the current iTotal CR Knee Replacement System. The proposed line extension consists of providing tibial inserts and patellae made from a highly cross linked Vitamin E infused polyethylene (iPoly XE) similar to the predicate Biomet E-Poly™ Tibial Bearings (K080528) and the DJO Surgical Highly Cross-Linked Vitamin E UHMWPE Tibial Insert and Patella (K113756, K103223, K091956).

The iPoly XE tibial inserts and patellae will be manufactured from ultra high molecular weight polyethylene (UHMWPE) that is blended with Vitamin E (alpha-tocopherol), compression molded and then highly cross-linked. Other than the material, the iPoly XE Tibial inserts are identical in design to those cleared for the iTotal CR KRS via **K120316**. The iPoly XE patellae are also identical in design to those cleared via **K112780**.

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 cutting of bone.

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	The function and general design features of the patient specific ancillary instruments remain similar to those described in the predicate iTotal CR 510ks (**K120316, K120068, K113378, K112780, K103117, K094050**).

Substantial Equivalence:	The product subject of this premarket notification is substantially equivalent in design and functionality to the iTotal Cruciate Retaining Knee Replacement System (**K112780** cleared December 15, 2011 and **K120316** cleared April 19, 2012). The iPoly XE tibial bearing material is similar to the material used in the Biomet E-Poly Tibial bearings (**K080528** cleared June 17, 2008), and the DJO Surgical Highly Cross-Linked UHMWPE Tibial Insert and Patella (**K091956** cleared September 28, 2010, **K103223** cleared December 21, 2010 and **K113756** cleared March 14, 2012)
	
	The following non-clinical laboratory testing was performed to determine substantial equivalence:
	
	• Material properties of iPoly XE
	  o Physical and Mechanical testing
	  o Chemical Analysis
	• Biocompatibility Testing of iPoly XE
	• Performance testing of iPoly XE inserts and patellae
	  o Wear testing
	  o Contact area/contact stress testing
	  o Tibial implant interlock testing
	  o Patella subluxation testing
	
	In-vitro knee simulator wear testing provided in the submission demonstrated that the iTotal CR KRS with iPoly XE exhibited a significant gravimetric wear reduction as compared to the iTotal CR KRS with conventional polyethylene tibial inserts. The results of *in-vitro* wear simulation testing have not been proven to quantitatively predict clinical wear performance.
	
	All testing has demonstrated the device is substantially equivalent to the predicate devices.

510(k) Summary continued
Device Comparison

Characteristic	iTotal CR KRS with iPoly XE (This submission)	Predicate iTotal CR KRS (K112780 and K 120316)	Biomet E-Poly Tibial Bearings K080528	Encore –DJO Surgical Highly Cross-linked Vitamin E UHMWPE Tibial Inserts and Patella K091956, K103223, K113756
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. • Revision procedures provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans. 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, 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 bi-compartmental implants. The implant is intended for cemented use only	Indications for Use: 1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis where one or more compartments are involved. 2. Correction of varus, valgus, or posttraumatic deformity. 3. Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure. For cemented and un-cemented use.	Joint replacement is indicated for patients suffering from disability due to: • degenerative, post-traumatic or rheumatoid arthritis; • avascular necrosis of the femoral condyle; • post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion dysfunction or prior patellectomy; • moderate valgus, varus or flexion deformities; • Treatment of fractures that are unmanageable using other techniques This device may also be indicated in the salvage of previously failed surgical attempts. This device is intended to be used with the 3DKnee System for cemented or uncemented applications. **Note:** Patella component is only intended for cemented use

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Characteristic	iTotal CR KRS with iPoly XE (This submission)	Predicate iTotal CR KRS (K112780 and K 120316)	Biomet E-Poly Tibial Bearings K080528	Encore –DJO Surgical Highly Cross-linked Vitamin E UHMWPE Tibial Inserts and Patella K091956, K103223, K113756
Intended for Cement Use Only	Yes	Yes	No	No
Product Classification	21 CFR 888.3560 (JWH)	21 CFR 888.3560 (JWH)	21 CFR 888.3560	21 CFR 888.3560
Materials	• Metal-Backed Tibial Components: o Tibial tray- CoCrMo o Tibial Insert-Vitamin E infused highly cross-linked UHMWPE • Patellar Component: Vitamin E infused highly cross-linked UHMWPE	• Metal-Backed Tibial Components: o Tibial tray- CoCrMo o Tibial Insert-UHMWPE • Patellar Component: UHMWPE	• Metal-Backed Tibial Components: o Tibial tray- CoCrMo o Tibial Insert-Vitamin E infused highly cross-linked UHMWPE • Patellar component- UHMWPE	• Metal-Backed Tibial Components: o Tibial tray- CoCrMo o Tibial Insert-Vitamin E infused highly cross-linked UHMWPE • Patellar component – Vitamin E infused highly cross-linked UHMWPE
Design	Knee joint patellofemorotibial semi – constrained cemented prosthesis	Knee joint patellofemorotibial semi – constrained cemented prosthesis	Knee joint patellofemorotibial semi –constrained cemented prosthesis	Knee joint patellofemorotibial polymer/metal!/polymer semi-constrained cemented prosthesis
Tibial Implant	• Configuration: Metal Backed Tibial Implant • Tibial Insert-Vitamin E infused highly cross-linked UHMWPE • Single or Dual inserts • Insert sizes:6-16mm • Profile: patient specific	• Configuration: Metal Backed Tibial Implant • Tibial Insert- UHMWPE • Single or Dual inserts • Insert sizes:6-16mm • Profile: patient specific	• Configuration: Metal Backed Tibial Implant • Tibial Insert-Vitamin E infused highly cross-linked UHMWPE • Single inserts • Five insert sizes – five thickness/size	• Configuration: Metal Backed Tibial Implant • Tibial Insert-Vitamin E infused highly cross-linked UHMWPE • Single inserts • 9 insert sizes (2- 12) and 5 thicknesses (9-19)
Instrumentation	Patient specific Nylon jigs	Patient specific Nylon jigs	Non Patient-specific jigs	Unknown
Principle of Operation	Cemented use Fixed Bearing Design	Cemented use Fixed Bearing Design	Cemented or un-cemented use Fixed Bearing Design	Cemented or un-cemented use Fixed Bearing Design
Posterior Cruciate Ligament (PCL) Sparing	Yes	Yes	Yes	Yes
Patient-Matched	Yes	Yes	No	No

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Characteristic	iTotal CR KRS with iPoly XE (This submission)	Predicate iTotal CR KRS (K112780 and K 120316)	Biomet E-Poly Tibial Bearings K080528	Encore –DJO Surgical Highly Cross-linked Vitamin E UHMWPE Tibial Inserts and Patella K091956, K103223, K113756
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	Unknown	Unknown
Sterility Method/ Assurance Level	VHP Gas Plasma $1x10^{-6}$	VHP Gas Plasma $1x10^{-6}$	Unknown	VHP Gas Plasma
Initial Shelf-Life	6 months	6 months	Unknown	Unknown
Labeled Non-pyrogenic	No	No	No	No

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Description and Conclusion of Testing

The determination of substantial equivalence for this device was based on a detailed device description and non-clinical laboratory testing. Testing on the iPoly XE outlined below:

Property /Characteristic	Tests conducted
Biocompatibility	Cytotoxicity, Sensitization, Intracutaneous Irritation, Systemic Toxicity, Material Mediated Pyrogenicity, Sub Chronic Toxicity, Genotoxicity, Muscle Implantation
Physical and Mechanical Properties	Small Punch Test, Fatigue Crack Growth Test, Izod Impact Test, Static Tensile Test, Compressive Modulus Test
Chemical Properties	Scanning Electron Microscopy analysis, Differential Scanning Calorimetry analysis, Free Radical Content, Oxidization Index, Extraction analysis, Residue on extraction, Uniformity of radiation dose, Cross-link Density, Vitamin E Content, Ash Content Environmental Stress Cracking,
Performance Testing	Tibiofemoral Contact Area/Stress, Strength of Tibial interlock, Patella Shear Test, Patella Tensile Test, Patellofemoral Contact Area/Stress Test, Wear Testing per ISO 14243. Wear Testing under abrasive conditions, Analysis of wear debris.
Electromagnetic Compatibility	Evaluation of the Safety and Compatibility of the iTotal CR Knee Replacement System within the MRI Environment
Test results demonstrated that the device is safe and can be considered substantially equivalent to the predicate device for the intended use.	

Safety and Performance

The determination of substantial equivalence for this device was based on a detailed device description and non-clinical laboratory testing. The testing demonstrated that the device is safe for its intended use and can be considered substantially equivalent to the predicate devices. 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 iPoly XE tibial inserts and patellae is substantially equivalent to the iTotal Cruciate Retaining Knee Replacement System **K112780** cleared December 15, 2011, **K120316** cleared April 19, 2012, **K080528 (Biomet)** cleared June 17, 2008, **K091956 (DJO Surgical)** cleared September 28, 2010, **K103223 (DJO Surgical)** cleared December 21, 2010, and **K113756 (DJO Surgical)** cleared March 14, 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

Conformis, Incorporated
% Ms. Amita Shah
Vice President, Quality & Regulatory Affairs
11 North Avenue
Burlington, Massachusetts 01803

Letter dated: January 14, 2013

Re: K122870
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: OIY, JWH, OOG
Dated: December 6, 2012
Received: December 7, 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): K122870

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.
- Revision procedures provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

The implant 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)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices

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