DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 14, 2016

ConforMIS, Incorporated
Ms. Amita Shah
Sr. Vice President, Regulatory and Quality Affairs
28 Crosby Drive
Bedford, Massachusetts 01730

Re: K161366
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, OIY
Dated: May 13, 2016
Received: May 17, 2016

Dear Ms. Amita 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 Parts 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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Lori A. Wiggins -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161366

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

Indications for Use *(Describe)*
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.
• Revision procedures provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

This implant is intended for cemented use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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8.0 510(K) SUMMARY (PAGE 1 OF 5)

Submitter's Name and Address:	ConforMIS, Inc. 28 Crosby Drive Bedford, MA 01730
Establishment Registration Number:	3009844603 and 3004153240
Date of Summary:	May 13, 2016
Contact Person: Telephone Number: Fax Number:	Amita S. Shah, Sr. Vice President, Regulatory and Quality Affairs (781) 345-9164 (781) 345-0147
Name of the Device:	ConforMIS iTotal® Cruciate Retaining Knee Replacement System (iTotal CR KRS)
Common Name:	Total Knee Replacement System
Regulatory Status and Regulation Number:	Class II 21 CFR 888.3560
Classification Name:	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Device Classification:	Product Code: JWH: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis. OOG: Knee Arthroplasty Implantation System. 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. OIY: prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer + additive/metal/polymer + additive. This generic type of device includes prosthesis that have a femoral component made 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 α-tocopherol.

510(K) SUMMARY (PAGE 2 OF 5)

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

This implant is intended for cemented use only.

Identification of the Legally Marketed Device (Predicate Device):

ConforMIS iTotal CR Knee Replacement System (ITOTAL CR KRS)

Device Class:	II
Product Code:	JWH, OOG, OIY
Regulation Number:	21 CFR 888.3560
510(k) Number:	K160025 & K122870

510(K) SUMMARY (PAGE 3 OF 5)

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.

Using patient imaging 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 either one or two polyethylene inserts. The polyethylene inserts may be manufactured from either UHMWPE or iPoly XE™ (a highly cross-linked vitamin E infused polyethylene) The patellar component is also manufactured from either UHMWPE or iPoly XE.

For user convenience, and similar to the predicate iTotal CR KRS, patient specific accessory orthopedic manual surgical instruments designed for use with the proposed iTotal CR KRS are provided to assist in the positioning of the total knee replacement components intraoperatively and in guiding the cutting of bone. In addition, reusable orthopedic manual surgical instruments are provided separately.

The function and general design features of the patient specific implants and ancillary instruments remain similar to those described in the predicate 510(k), K160025.

510(K) SUMMARY (PAGE 4 OF 5)

Comparison Summary of Technological Characteristics and Modifications Proposed:

The proposed iTotal CR KRS and predicate iTotal CR KRS have the same technological characteristics. There have been no changes to the proposed iTotal CR KRS devices with respect to design, materials, and methods of manufacture, or packaging. The designs of the devices remain similar to those cleared via K160025.

This submission proposes the addition of ethylene oxide sterilization as an alternative sterilization method for the iPoly XE components. The iPoly XE components of the iTotal CR KRS are cleared for sterilization via VHP (Gas Plasma) (K122870). EO Sterilization was cleared as an alternative method of sterilization for the iTotal CR KRS (K133256).

Table 8.0-1: Comparison Between the Proposed and Predicate Implant Components

Component Material	Predicate iTotal CR KRS (K160025)	Proposed iTotal CR KRS (This submission)
CrCoMo Femoral and Tibial Implant	Sterilized via VHP (Gas Plasma) or Ethylene Oxide to an SAL of $1.0x10^{-6}$	Sterilized via VHP (Gas Plasma) or Ethylene Oxide to an SAL of $1.0x10^{-6}$
UHMWPE Tibial Inserts and Patella	Sterilized via VHP (Gas Plasma) or Ethylene Oxide to an SAL of $1.0x10^{-6}$	Sterilized via VHP (Gas Plasma) or Ethylene Oxide to an SAL of $1.0x10^{-6}$
iPoly XE (Vitamin E infused highly cross-linked UHMWPE) Tibial Inserts and Patella	Sterilized via VHP (Gas Plasma) to an SAL of $1.0x10^{-6}$	Sterilized via VHP (Gas Plasma) or Ethylene Oxide to an SAL of $1.0x10^{-6}$

Substantial Equivalence:

The proposed iTotal CR KRS is substantially equivalent to the predicate iTotal CR KRS (K160025 cleared March 7, 2016 and K122870 cleared January 14, 2013). The following non-clinical testing was performed to establish substantial equivalence:

- Sterilization Validation to confirm a Sterility Assurance Level (SAL) of $1.0x10^{-6}$
- Ethylene Oxide (EO) Residual Testing
- Mechanical, Material, and Chemical Property Testing Post-EO Sterilization for iPoly XE
- Non-pyrogenic status for the iTotal CR was determined using the LAL test method with an identified acceptable testing limit of <20 EU/Device. Controls are in place to monitor relevant manufacturing processes for endotoxin. Endotoxin testing of final sterilized devices is performed on a routine basis.

510(K) SUMMARY (PAGE 5 OF 5)

Conclusion: Based on the testing conducted, it is concluded that the proposed iTotal Cruciate Retaining Knee Replacement System is substantially equivalent to the predicate device, the iTotal Cruciate Retaining Knee Replacement System (K160025 cleared March 7, 2016 and K122870 cleared on January 14, 2013). The components manufactured from the iPoly XE material can be sterilized to an SAL of $1.0x10^{-6}$ using Ethylene Oxide sterilization.