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

March 7, 2016

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

Re: K160025
Trade/Device Name: ConforMIS iTotal Cruciate Retaining Knee Replacement System, ConforMIS iTotal Posterior Stabilized 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, OIY
Dated: February 11, 2016
Received: February 16, 2016

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 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,

Mark N. Melkerson -S

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)*

K160025

Device Name

ConforMIS iTotal Cruciate Retaining Knee Replacement System

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 structurs 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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)*

K160025

Device Name

ConforMIS iTotal Posterior Stabilized Knee Replacement System

Indications for Use *(Describe)*

The iTotal PS 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, polyarthritis, or osteonecrosis of the knee
- Post traumatic loss of joint function
- Moderate varus, valgus, or flexion deformity
- 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 4)

Submitter's Name and Address:	ConforMIS, Inc. 28 Crosby Drive Bedford, MA 01730
Establishment Registration Number:	3009844603 and 3004153240
Date of Summary:	January 5, 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(s):	ConforMIS iTotal® Cruciate Retaining Knee Replacement System (iTotal CR KRS) ConforMIS iTotal® Posterior Stabilized Knee Replacement System (iTotal PS KRS)
Common Name(s):	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 Codes: 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 4)

Indications for Use:

iTotal CR KRS

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.

iTotal PS KRS

The iTotal PS 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, polyarthritis or osteonecrosis of the knee.
- Post traumatic loss of joint function.
- Moderate varus, valgus or flexion deformity.
- 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.

510(K) SUMMARY (PAGE 3 OF 4)

Identification of the Legally Marketed Device(s) (Predicate Device(s)):	ConforMIS iTotal CR Knee Replacement System Device Class: II Product Code: JWH, OOG, OIY Regulation Number: 21 CFR 888.3560 510(k) Number: K142161, K142404 and K152704 ConforMIS iTotal PS Knee Replacement System Device Class: II Product Code: JWH, OOG, OIY Regulation Number: 21 CFR 888.3560 510(k) Number: K142161, K142404 and K152704
Device Description:	The iTotal® Knee Replacement Systems (hereafter referred to as the "iTotal KRS") are patient specific tricompartmental faceted knee replacement systems. The iTotal® KRS are semi-constrained, cemented knee implants which consist of femoral, tibial, and patellar components. 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 single or dual-piece (CR only) polyethylene inserts. The polyethylene inserts may be manufactured from either UHMWPE, or for iTotal CR KRS, a highly cross-linked Vitamin E infused polyethylene (iPoly XE) The patellar component is also manufactured from either UHMWPE or from a highly cross-linked Vitamin E infused polyethylene (iPoly XE). For user convenience, and similar to the predicate iTotal KRS, accessory orthopedic manual surgical instruments designed for use with the modified iTotal KRS are provided to assist with implantation. The ancillary instruments may be provided sterile or non-sterile to be sterilized by the end-user and are for single-use only. The purpose of this submission is to propose dimensional modifications to the iTotal KRS implants and changes to the ancillary instrumentation. The function and general design features of the patient specific implants and ancillary instruments remain similar to those described in the predicate 510(k)'s K142161, K142404 and K152704.

510(K) SUMMARY (PAGE 4 OF 4)

Comparison Summary of Technological Characteristics and Modifications Proposed:	The modified iTotal KRS and predicate iTotal KRS have the same technological characteristics. The modified iTotal KRS consists of dimensional modifications to the iTotal KRS implants and changes to the ancillary instrumentation, but there have been no changes to the intended use or function. The materials, methods of manufacture, and packaging remain similar to those cleared via K142161, K142404 and K152704. The following non-clinical laboratory tests were performed to determine substantial equivalence: • Tibial Insert Spine-Femoral Cam Fatigue Testing • Range of Motion Analysis • Cadaveric Evaluation
Substantial Equivalence:	Nonclinical Testing: The determination of substantial equivalence for this device was based on a detailed device description and non-clinical laboratory testing. The following non-clinical laboratory tests were performed to determine substantial equivalence: • Tibial Insert Spine-Femoral Cam Fatigue Testing • Range of Motion Analysis • Cadaveric Evaluation Test results demonstrated that the device is substantially equivalent to the predicate devices for their intended use.
Conclusion:	The determination of substantial equivalence for these devices was based on detailed device descriptions. Non-clinical laboratory testing was performed demonstrating that the devices can be considered substantially equivalent to the predicate devices for the intended uses. Clinical data is not necessary to demonstrate substantial equivalence. Based on the testing conducted, it is concluded that the iTotal Cruciate Retaining and Posterior Stabilized Knee Replacement Systems are substantially equivalent to the predicate devices: the iTotal Cruciate Retaining and Posterior Stabilized Knee Replacement Systems (K142161, cleared November 14, 2014, K142404, cleared December 11, 2014 and K152704, cleared October 21, 2015).