



Food and Drug Administration
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Conformis, Incorporated
Ms. Amita Shah
Senior Vice President, Regulatory and Quality Affairs
28 Crosby Drive
Bedford, Massachusetts 01730

July 15, 2016

Re: K161668

Trade/Device Name: ConforMIS iTotal[®] Posterior Stabilized (PS) Knee Replacement System (iTotal PS)

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: June 13, 2016

Received: June 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 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 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" (21 CFR 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,

Mark N. Melkerson -S

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)

K161668

Device Name

ConforMIS iTotal® PS Knee Replacement System (iTotal PS)

Indications for Use (Describe)

The iTotal® PS 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 unicompartmental, patellofemoral or bicompartamental 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 unicompartmental, patellofemoral or bicompartamental 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:	June 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(s):	ConforMIS iTotal® PS Knee Replacement System (iTotal PS)
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 prostheses 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® Posterior Stabilized (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 bicompartamental 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 bicompartamental 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(s) (Predicate
Device(s)):**

ConforMIS iTotal PS Knee Replacement System (ITOTAL PS KRS)
Device Class: II
Product Code: JWH, OOG, OIY
Regulation Number: 21 CFR 888.3560
510(k) Number: K160025 & K153217

510(K) SUMMARY (PAGE 3 OF 5)

Device Description:

The iTotal Posterior Stabilized Knee Replacement System (hereafter referred to as the "iTotal PS KRS") is a patient specific tricompartmental faceted, cruciate sacrificing knee replacement system. The iTotal PS KRS is a semi-constrained, fixed bearing, cemented knee implant which consists of a femoral, tibial and patellar component.

Using patient imaging (CT scan) 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 a polyethylene insert that is manufactured from ultra-high molecular weight polyethylene (UHMWPE). The patellar component is 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 PS KRS, patient specific accessory orthopedic manual surgical instruments designed for use with the proposed iTotal PS KRS are provided to assist in the positioning of the total knee replacement components intraoperatively and in guiding the cutting of bone. These instruments are single use only and may be provided sterile. 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)s K160025 & K153217.

510(K) SUMMARY (PAGE 4 OF 5)

Comparison Summary of Technological Characteristics and Modifications Proposed:

The proposed iTot PS KRS and predicate iTot PS KRS have the same technological characteristics. There have been no changes to the proposed iTot PS KRS device with respect to design, materials and methods of manufacture, packaging, or sterilization. The designs of the device remains similar to that cleared in K160025 and K153217.

Modifications which represent improving manufacturing efficiencies are primarily focused on adding the option of automating the generation of the iTot PS iJigs using the proprietary software modules iTot FemJigs PS v1.0 and iTot TibJigs PS v1.0.

Table 8.0-1: Comparison Between the Proposed and Predicate Device

Characteristic	Predicate iTot PS KRS (K160025 and K153217)	Proposed iTot PS KRS (This submission)
Generation of iTot PS Femoral iJigs	iTot FemJigs v3.0 and Manual process	iTot FemJigs PS v1.0 or Manual process
Generation of iTot PS Tibial iJigs	Manual process	iTot TibJigs PS v1.0 or Manual process

510(K) SUMMARY (PAGE 5 OF 5)

Substantial Equivalence: 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 can be considered substantially equivalent to the predicate device for the intended use. The following non-clinical laboratory testing was performed:

- Detailed software description and software verification and validation testing of proprietary software iTotal FemJigs PS v1.0.
- Detailed software description and software verification and validation testing of proprietary software iTotal TibJigs PS v1.0.

Conclusion: Based on the testing conducted, it is concluded that the proposed iTotal Posterior Stabilized Knee Replacement System is substantially equivalent to the predicate iTotal Posterior Stabilized Knee Replacement System (K160025, cleared March 07, 2016, and K153217, cleared January 07, 2016).