



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

October 21, 2015

Re: K152704

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: September 18, 2015

Received: September 21, 2015

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" (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

## Indications for Use

510(k) Number (if known)

K152704

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 bicompartamental 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 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.

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

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## Indications for Use

510(k) Number (if known)

K152704

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 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.

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 3001153240
Date of Summary:	September 18, 2015
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 Cruciate Retaining Knee Replacement System Total Posterior Stabilized Knee Replacement System
Regulatory Status and Regulation Number:	Class II 21 CFR 888.3560
Classification Name:	Knee joint patellofemoral tibial polymer/metal/polymer semi-constrained cemented prosthesis
Device Classification:	Product Codes: JWH: Knee joint patellofemoral tibial 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, patellofemoral tibial, 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 $\alpha$ -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 bicompartamental 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 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.

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 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.

**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 and K142404

ConforMIS iTotal PS Knee Replacement System  
 Device Class: II  
 Product Code: JWH, OOG, OIY  
 Regulation Number: 21 CFR 888.3560  
 510(k) Number: K142161 and K142404

**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 and for single-use only. The purpose of this submission to propose the alternative option to provide these single-use, disposable iTotal iJig instruments non-sterile to be steam sterilized by the end-user. 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.

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** and **K142404**.

**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. There have been no changes to the modified iTotal KRS devices with respect to the intended use and function. The design, materials, and methods of manufacture and packaging remain similar to those cleared via **K142161** and **K142404**.

This submission proposes an alternative option to provide the iTotal iJig instrumentation as non-sterile to be steam sterilized by the end-user. The implants will continue to be provided sterile as currently cleared (**K142161** and **K142404**).

**Table 8.0-1: Comparison Between the Predicate and Modified Devices**

How Supplied	iTotal Implants	iTotal iJig Instrumentation
Predicate Devices ( <b>K142161</b> & <b>K142404</b> )	Provided sterile via VHP (gas plasma) or EO to an SAL of $1 \times 10^{-6}$	Provided sterile via VHP (gas plasma) or EO to an SAL of $1 \times 10^{-6}$
This Submission	Provided sterile via VHP (gas plasma) or EO to an SAL of $1 \times 10^{-6}$	Provided sterile via VHP (gas plasma) or EO to an SAL of $1 \times 10^{-6}$ <b>OR</b> Provided non-sterile to be steam sterilized by the end-user*

\*The following currently marketed systems provide non-sterile, patient-specific instruments:

- Signature Patient-Specific Surgical Guides (**K140257**)
- Visionaire (**K143226**)

**Substantial Equivalence:**

The products subject of this premarket notification are substantially equivalent to the iTotal CR and PS KRS (**K142161**, cleared November 14, 2014 and **K142404**, cleared December 11, 2014). The following testing was performed to establish substantial equivalence:

- Steam Sterilization Validation to a Sterility Assurance Level (SAL) of  $1 \times 10^{-6}$
- Product Integrity Testing Post-Steam Sterilization

**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 modified iTotal KRS are substantially equivalent to the predicate iTotal KRS (**K142161**, cleared November 14, 2014 and **K142404**, cleared December 11, 2014).