February 17, 2021

Conformis Inc.
Mary Kruitwagen
Sr. Regulatory Affairs Specialist
600 Technology Park Drive, 4th Floor
Billerica, Massachusetts 01821

Re: K210252
Trade/Device Name: iTotal Identity® Cruciate Retaining (CR) Knee Replacement System, iTotal Identity® Posterior Stabilizing (PS) 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, OIY, OOG
Dated: January 25, 2021
Received: January 29, 2021

Dear Mary Kruitwagen:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ting Song, Ph.D., R.A.C.
Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K210252

Device Name

iTotal Identity Cruciate Retaining (CR) Knee Replacement System

Indications for Use *(Describe)*

The iTotal Identity Cruciate Retaining (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 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 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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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name

iTotal Identity Posterior Stabilizing (PS) 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 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.

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)

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510(K) Summary

Subject Device: (Proprietary/Trade name):	iTotal Identity® Cruciate Retaining (CR) Knee Replacement System iTotal Identity® Posterior Stabilized (PS) Knee Replacement System
Common Usual Name:	Knee Replacement System
Type of Submission:	Special 510(k)
Device Class:	II
Regulation Number:	888.3560
Regulation Description:	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Primary Product Classification (Product Code) and Description:	JWH Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Secondary Product Classifications (Product Code) and Descriptions:	OOG, OIY Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Reviewing Agency:	Orthopedics
Date of Summary Preparation:	January 27, 2021
Submitter's Name and Address:	Conformis Inc. 600 Technology Park Drive Fourth Floor Billerica, MA 01821 USA
Telephone Number:	781-345-9001
Establishment Registration Number(s):	3009844603 3004153240
Contact Name:	Mary Kruitwagen
Contact Telephone:	781-345-9038
Contact email:	Mary.Kruitwagen@conformis.com
Alternate Contact:	Kara Johnson
Alternate Contact Telephone:	781-832-5402
Alternate Contact email:	Kara.Johnson@conformis.com
Primary Predicate Device:	iTotal Identity® Cruciate Retaining (CR) Knee Replacement System iTotal Identity® Posterior Stabilized (PS) Knee Replacement System
Primary Predicate Device 510(k):	K203447; December 22, 2020
Primary Predicate Device Product Classification (ProCode) and Description:	JWH, OOG, OIY Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis

Secondary Predicate Device:	iUni Unicondylar Knee Replacement System, iDuo Bicompartmental Knee Repair System, iTotal CR Knee Replacement System, iTotal PS Knee Replacement System
Secondary Predicate Device 510(k):	K193105; March 13, 2020
Secondary Predicate Device Classification (ProCode) and Description:	JWH, OOG, OIY, NPJ, HSX Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis

Modification

This submission is to seek clearance for use of an additional sterilization process for the subject devices iTotal Identity® Cruciate Retaining (CR) Knee Replacement System and iTotal Identity® Posterior Stabilized (PS) Knee Replacement System. This submission seeks to add Vaporized Hydrogen Peroxide Low-Temperature Sterilant-Vacuum (VHP LTS-V) to the portfolio of sterilization processes for the subject devices. There are no device modifications.

Device Description

iTotal Identity® Cruciate Retaining (CR) Knee Replacement System (KRS) and iTotal Identity® Posterior Stabilized (PS) Knee Replacement System (KRS) are patient specific tri-compartmental faceted knee replacements systems. The iTotal Identity CR KRS is a faceted posterior cruciate ligament retaining knee replacement system. It is a semi-constrained, cemented knee implant which consists of femoral, tibial, and patellar components. iTotal Identity® PS KRS is a semi-constrained, cemented knee implant consisting of femoral, tibial, patellar and articular tibial insert 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 and tray keel stem extension manufactured from titanium (Ti6AL4V-ELI) alloy, a tibial tray keel (stem) cap manufactured from polyethylene (UHMWPE) and either one or two polyethylene inserts (Two piece is available with the CR KRS only). The polyethylene inserts may be manufactured from either UHMWPE (iPoly®) or iPoly® XE (a highly cross-linked vitamin E stabilized UHMWPE). The patellar component is provided in either a round or oval dome shape and may be manufactured from either UHMWPE or iPoly® XE.

For user convenience, single-use, patient-specific ancillary orthopedic manual surgical instruments designed for use with the proposed iTotal Identity® CR KRS or iTotal Identity® PS 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.

Indications for Use

iTotal Identity® Cruciate Retaining (CR) Knee Replacement System

The iTotal Identity® Cruciate Retaining (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 Identity® Posterior Stabilized (PS) Knee Replacement System

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.

Technological Characteristics

The proposed and predicate devices are cemented knee implants that consist of three primary components; femoral, tibial, and patellar implants. Single-use, patient-specific ancillary surgical instruments are provided for use to assist with surgical implantation. Reusable ancillary surgical instruments, provided in a reusable instrument tray, assist with surgical implantation.

The subject devices iTotal Identity Cruciate Retaining (CR) Knee Replacement System and iTotal Identity® Posterior Stabilized (PS) Knee Replacement System are the same as the predicate devices with regards to:

- Indications for Use
- Device design

- Device usage
- Operating principles
- Packaging
- Sterilization processes (methods)
- Biocompatibility
- Shelf-life
- Materials of composition

The modification is to add an additional sterilization process (method) for the subject devices. There are no design changes to the subject device beyond the added sterilization process. The manufacture of the subject device is unchanged from that described in the 510(k) submissions of the predicate devices.

Performance Data

Non-clinical testing was performed including sterilization and risk-based biocompatibility testing. The results support that the device components are effectively sterilized using VHP LTS-V.

Testing includes:

- Sterilization Validation testing to establish a SAL of $1x10^{-6}$
- VHP Residual Testing

The testing results conclude that the addition of the use of VHP LTS-V sterilization raises no new issues regarding safety or effectiveness. The performance of the subject devices sterilized by VHP LTS-V is expected to be the same as the currently marketed predicate devices.

Substantial Equivalence

The modification to add an additional sterilization process shows equivalency to the VHP LTS-V sterilization as described in the secondary predicate. Results support that the VHP LTS-V sterilized subject devices would be equivalent to the primary predicate devices using currently cleared sterilization processes (EO, VHP gas plasma). No new issues of safety and effectiveness were raised.

Conclusion

Based on the results of the testing performed, the subject iTotal Identity® Cruciate Retaining (CR) Knee Replacement System and iTotal Identity® Posterior Stabilized (PS) Knee Replacement System, are substantially equivalent to the predicate devices iTotal Identity® Cruciate Retaining (CR) Knee Replacement System and iTotal Identity® Posterior Stabilized (PS) Knee Replacement System and can be sterilized to a SAL of 1x10-6 utilizing VHP LTS-V sterilization.