May 12, 2021

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

Re: K210809
Trade/Device Name: iTotal® Identity™ Cruciate Retaining (CR) Knee Replacement System (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: March 15, 2021
Received: March 17, 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)*
K210809

Device Name
iTotal® Identity™ Cruciate Retaining (CR) Knee Replacement System (KRS)

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 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. The CS insert option should be utilized when additional anterior-posterior constraint is desired.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5: 510(k) Summary

The following 510(k) Summary is provided as per 21 CFR 807.92 requirements

Subject Device: (Proprietary/Trade name):	iTotal® Identity™ Cruciate Retaining (CR) Knee Replacement System (KRS)
Common Usual Name:	Knee Replacement System
Type of Submission:	Traditional 510(k)
Device Class:	II
Regulation Number:	888.3560
Regulation Description:	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Primary Product Classification Code and Description:	JWH Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Secondary Product Classifications Code(s) and Description(s):	OOG, OIY Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Reviewing Agency:	Orthopedics
Date of Summary Preparation:	March 15, 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:	Emmanuel Nyakako
Alternate Contact Telephone:	781-345-9164
Alternate Contact email:	Emmanuel.Nyakako@conformis.com
Primary Predicate Device:	iTotal® Identity™ Cruciate Retaining (CR) Knee Replacement System iTotal® Identity™ Posterior Sacrificing (PS) Knee Replacement System
Primary Predicate Device 510(k):	K203447, December 22, 2020

Primary Predicate Device Product Classification Code(s) and Description(s):	JWH, OOG, OIY Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Secondary Predicate Device:	iTotal® Identity™ Cruciate Retaining (CR) Knee Replacement System iTotal® Identity™ Posterior Stabilized (PS) Knee Replacement System
Secondary Predicate Device 510(k):	K210252, February 18, 2021
Secondary Predicate Device Product Classification Code(s) and Description(s):	JWH, OOG, OIY Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Reference Device:	Stryker Orthopeadics Triathlon Total Knee System
Reference Device 510(k):	K173849, February 2, 2018
Reference Device Product Classification Code(s) and Description(s):	MBH: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis., JWH: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis

Modification	This submission requests 510(k) clearance for the Cruciate Sacrificing (CS) tibial insert utilized with iTotal® Identity™ Cruciate Retaining (CR) Total Knee Replacement System (KRS). This optional insert may be used when additional anterior-posterior constraint is desired. Included in this submission are the corresponding CS trials.
Device Description	iTotal® Identity™ Cruciate Retaining (CR) Knee Replacement System (KRS) is a patient-specific tri-compartmental faceted knee replacement system. It is a posterior cruciate ligament retaining knee replacement system. It is a semi-constrained, cemented knee implant which consists of femoral, tibial, and patellar components. An optional Cruciate Sacrificing insert may be utilized when additional anterior-posterior constraint is desired. Using patient imaging (CT scans) 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 cap manufactured from polyethylene (UHMWPE) and either one or two polyethylene inserts. The CS insert is a one-piece insert. The polyethylene inserts may be manufactured from either iPoly® (UHMWPE) 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 iPoly® 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 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

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. The CS insert option should be utilized when additional anterior-posterior constraint is desired.

Technological Characteristics

<u>Intended Use/Indications for Use:</u>
The proposed Cruciate Sacrificing (CS) tibial insert utilized with iTotal® Identity™ Cruciate Retaining (CR) Knee Replacement System (KRS), is indicated when the surgeon desires additional anterior-posterior constraint. This does not change the intended use of the device, only clarifies the purpose of the subject CS insert within the context of the Indications for Use. While the intended use of the device has not changed, the Indications for Use is modified to include the following statement: *The CS insert option should be utilized when additional anterior-posterior constraint is desired*.

<u>Operating Principal/Fundamental Technology</u>:
The proposed and predicate devices are semi-constrained, cemented knee implants that consist of three primary components; femoral, tibial, and patellar.

Single-use, patient-specific ancillary surgical instruments are provided for use with both the predicate and proposed iTotal® Identity™ CR KRS to assist with surgical implantation.

Reusable ancillary surgical instruments, provided in a reusable instrument tray, are used with the predicate and proposed devices. These instruments assist with surgical implantation.

Design:
The proposed and predicate devices have the same basic design characteristics as they are comprised of three primary components: femoral, tibial, and patellar. The proposed Cruciate Sacrificing insert utilized with iTotal® Identity™ CR KRS offers an option when additional anterior-posterior constraint is desired.

Materials:
The femoral implant is CoCrMo alloy. The Tibial tray and stem are titanium alloy (Ti6AL4V-ELI) with the stem cap of UHMWPE. The tibial insert, including the subject insert, is iPoly® or iPoly® XE. The trials and ancillary single-use instruments are Nylon. Reusable ancillary surgical instruments are R-Radel or stainless steel.

Sterilization:
The subject and predicates devices are provided sterile utilizing Ethylene Oxide (EO) or Vaporized Hydrogen Peroxide Low Temperature Sterilant-Vacuum process.

Performance Data

The following testing was conducted using the subject CS insert to verify that the device is substantially equivalent to the predicate iTotal® Identity™ Cruciate Retaining (CR) Knee Replacement System (KRS).

- Contact Area and Surface testing
- Constraint analysis
- Range of Motion
- Tibial interlock strength
- Cadaveric evaluation

Design validation was conducted under simulated use conditions. It consisted of cadaveric testing following the proposed surgical technique for the proposed iTotal® Identity™ CR KRS with CS Insert.

The test results demonstrated that the proposed iTotal Identity CR KRS is safe for its intended use and can be considered substantially equivalent to the predicate iTotal® Identity™ Cruciate Retaining (CR) Knee Replacement System (KRS).

Substantial Equivalence

The proposed Cruciate Sacrificing (CS) tibial insert utilized with iTotal® Identity™ Cruciate Retaining (CR) Knee Replacement System (KRS), is indicated when the surgeon desires additional anterior-posterior constraint. While the intended use of the Knee Replacement System has not changed, the Indications for Use is modified to include the following statement: The CS insert option should be utilized when additional anterior-posterior constraint is desired. This statement does not change the intended use of the device, only clarifies the purpose of the subject CS insert within the context of the Indications for Use.

The subject device, Cruciate Sacrificing (CS) tibial insert utilized with iTotal® Identity™ Cruciate Retaining (CR) Knee Replacement System, is the same as the predicate device with regards to:

- Intended Use
- operating principles
- femoral implant
- tibial implant
- CR tibial insert
- patella component
- ancillary instruments and iJigs
- design and methods of manufacture of the implants and instrumentation
- packaging configurations
- performance characteristics
- sterilization methods
- sterility assurance level (SAL) of $1x10^{-6}$

Conclusion

Based on the intended use, technological characteristics, and outcome of the performance data the subject device, subject Cruciate Sacrificing (CS) tibial insert utilized with iTotal® Identity™ Cruciate Retaining (CR) Knee Replacement System (KRS) is substantially equivalent to the primary and secondary predicate device iTotal® Identity™ Cruciate Retaining (CR) Knee Replacement System.