July 17, 2023

Conformis, Inc.
Nancy Giezen
Manager Regulatory Affairs
600 Technology Park Dr.
Billerica, Massachusetts 01830

Re: K230846
Trade/Device Name: iTotal Identity Cruciate Retaining (CR) Knee Replacement System (KRS);
iTotal Identity Posterior Stabilizing (PS) Knee Replacement System (KRS);
Identity Imprint Cruciate Retaining (CR) Knee Replacement System (KRS);
Identity Imprint Posterior Stabilizing (PS) 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, OIY, OOG
Dated: March 27, 2023
Received: June 15, 2023

Dear Nancy Giezen:

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,

Lixin Liu -S

Lixin Liu, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230846

Device Name
iTotal Identity Cruciate Retaining (CR) Knee Replacement System (KRS), iTotal Identity Posterior Stabilizing (PS) Knee Replacement System (KRS), Identity Imprint Cruciate Retaining (CR) Knee Replacement System (KRS), Identity Imprint Posterior Stabilizing (PS) Knee Replacement System (KRS)

Indications for Use *(Describe)*

iTotal Identity Cruciate Retaining (CR) Knee Replacement System (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.
The CS (cruciate sacrificing) insert option should be utilized when additional anterior-posterior constraint is desired.

iTotal Identity Posterior Stabilizing (PS) Knee Replacement System (KRS)
The iTotal Identity Posterior Stabilized 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 unicondylar, patellofemoral or bicompartmental prosthesis.
The Indications for Use include:
Painful joint disease due to osteoarthritis, traumatic arthritis, rheumatoid arthritis, polyarthritis, 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.

Identity Imprint Cruciate Retaining (CR) Knee Replacement System (KRS)
The Identity™ Imprint™ CR Total 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 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.

Identity Imprint Posterior Stabilizing (PS) Knee Replacement System (KRS)
The Identity™ Imprint™ PS Total 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 unicondylar, patellofemoral or bicompartmental prosthesis.
The Indications for Use include:
Painful joint disease due to osteoarthritis, traumatic arthritis, rheumatoid arthritis, polyarthritis, 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.

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."

CONFORMIS

510(k) Summary

Prepared on: 2023-07-17

Contact Details

Applicant Name:	Conformis, Inc.
Applicant Address:	600 Technology Park Dr. Billerica MA 01830 United States
Applicant Contact Telephone:	(781) 345-9058
Applicant Contact:	Nancy Giezen
Applicant Contact Email:	Nancy.Giezen@conformis.com

Device Name

Device Trade Name:

iTotal Identity Cruciate Retaining (CR) Knee Replacement System (KRS)
iTotal Identity Posterior Stabilizing (PS) Knee Replacement System (KRS)
Identity Imprint Cruciate Retaining (CR) Knee Replacement System (KRS)
Identity Imprint Posterior Stabilizing (PS) Knee Replacement System (KRS)

Common Name:

Knee replacement system

Classification Name:

Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis

Regulation Number:

888.3560

Product Code:

JWH, OIY, OOG

Legally Marketed Predicate Devices

Predicate #:	Predicate Trade Name:	Product Codes:
K210809	iTotal Identity Cruciate Retaining (CR) Knee Replacement System (KRS)	JWH, OIY, OOG
K210252	iTotal Identity Posterior Stabilizing (PS) Knee Replacement System (KRS)	JWH, OIY, OOG
K221404	Identity Imprint Cruciate Retaining (CR) Knee Replacement System (KRS)	JWH, OIY, OOG
	Identity Imprint Posterior Stabilizing (PS) Knee Replacement System (KRS)	JWH, OIY, OOG

Device Description Summary

The iTotal Identity and Identity Imprint Knee Replacement Systems (KRS) are semi-constrained total knee prosthetic devices consisting of femoral, tibial, and patellar components. These devices are intended for treatment of severe pain and/or disability of a knee damaged by osteoarthritis or trauma.

Patient imaging (CT scans) can be used to design patient-specific implants (iTotal Identity) or to select standard sized implants (Identity Imprint), to meet the geometric and anatomic requirements of the specific patient. The femoral components of the subject devices are manufactured from cobalt chromium molybdenum (CoCrMo) alloy. The tibial component includes a metal tray manufactured from titanium alloy and polyethylene inserts. The patellar components are manufactured from UHMWPE.

For user convenience, single-use, patient-specific surgical instruments 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.

Intended Use/Indications For Use

iTotal Identity Cruciate Retaining (CR) Knee Replacement System (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.

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

iTotal Identity Posterior Stabilizing (PS) Knee Replacement System (KRS)
The iTotal Identity Posterior Stabilized 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 unicondylar, patellofemoral or bicompartmental prosthesis.

The Indications for Use include:
Painful joint disease due to osteoarthritis, traumatic arthritis, rheumatoid arthritis, polyarthritis, 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.

Identity Imprint Cruciate Retaining (CR) Knee Replacement System (KRS)
The Identity™ Imprint™ CR Total 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 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.

Identity Imprint Posterior Stabilizing (PS) Knee Replacement System (KRS)
The Identity™ Imprint™ PS Total 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 unicondylar, patellofemoral or bicompartmental prosthesis.

The Indications for Use include:
Painful joint disease due to osteoarthritis, traumatic arthritis, rheumatoid arthritis, polyarthritis, 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.

Indications For Use Comparison
The indications for use are the same as compared with the predicate devices.

Technological Comparison
The subject devices which include the implants, single-use patient-specific instruments and reusable instruments remain identical to the predicate devices in operating principle, fundamental technology, design and materials. The purpose of this submission is to incorporate software updates to improve manufacturing efficiencies.

Non-Clinical and/or Clinical Test Summary and Conclusions
The results of verification and validation testing confirmed that the software performed as well as or better than the predicates. No different questions of safety or effectiveness were raised. Thus the subject devices are considered substantially equivalent to the predicate devices.