April 27, 2023

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

Re: K230844
Trade/Device Name: Identity Imprint Cruciate Retaining (CR) Knee Replacement System (KRS) with Cruciate Sacrificing (CS) Insert
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 24, 2023
Received: March 28, 2023

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,

Jesse Muir -S

Jesse Muir, Ph.D.
Acting 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.

Submission Number *(if known)*

K230844

Device Name

Identity Imprint Cruciate Retaining (CR) Knee Replacement System (KRS) with Cruciate Sacrificing (CS) Insert

Indications for Use *(Describe)*

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. 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.

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510(k) Summary

Submitter's Name and Address:	Conformis, Inc. 600 Technology Park Drive, Fourth Floor Billerica, MA 01821 USA
Establishment Registration Number(s):	3009844603 and 3004153240
Date Summary was Prepared:	March 24, 2023
Contact Person:	Mary Kruitwagen Sr. Regulatory Affairs Specialist
Contact Information:	Mary.Kruitwagen@conformis.com 781-345-9038
Trade/Device Name(s)	Identity™ Imprint™ Cruciate Retaining (CR) Knee Replacement System (KRS) with Cruciate Sacrificing (CS) Insert
Common Name:	Knee Replacement System
Device Class:	Class 2
Regulation Number(s)	21 CFR 888.3560
Classification Names and Product Codes:	Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer (JWH) Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer + Additive/Metal/Polymer + Additive (OIY) Knee Arthroplasty Implantation System (OOG)
Primary Predicate Device:	K210809 iTotal® Identity™ Cruciate Retaining (CR) Knee Replacement System (with CS insert)
Primary Predicate Regulation Number(s)	21 CFR 888.3560
Primary Predicate Classification Names and Product Codes:	Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer (JWH) Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer + Additive/Metal/Polymer + Additive (OIY) Knee Arthroplasty Implantation System (OOG)
Secondary Predicate Device:	K221404 Identity Imprint Cruciate Retaining Knee Replacement System
Reference Predicate Regulation Number(s)	21 CFR 888.3560
Reference Predicate Classification Names and Product Codes:	Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer (JWH) Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer + Additive/Metal/Polymer + Additive (OIY) Knee Arthroplasty Implantation System (OOG)

Device Description:

The subject device, Identity Imprint Cruciate Retaining (CR) Knee Replacement System (KRS) with Cruciate Sacrificing (CS) Insert, is a knee replacement system including standardized implant sizes combined with standard and patient-specific ancillary surgical instrumentation. As with all Conformis Knee Replacement Systems (KRS), the Identity Imprint Knee Replacement System is semi-constrained knee implants which consist of a femoral, tibial, and/or patellar components. The products are intended for treatment of severe pain and/or disability of the knee damaged by osteoarthritis or trauma.

Using patient imaging (either CT or MR scans), a standard implant is selected that best meets 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, standard and patient-specific ancillary orthopedic manual surgical instruments designed for use with the selected Identity Imprint implants 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.

This submission also seeks clearance of Cruciate Sacrificing (CS) Insert to be used with the cleared (secondary predicate) Identity Imprint Cruciate Retaining (CR) Knee Replacement System (KRS).

Indications for Use:

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

Technological Characteristics:

The focus of this submission is on clearance of Cruciate Sacrificing tibial insert of iPoly™ XE offered in thicknesses of 6mm to 18mm to compatible with Identity Imprint Cruciate Retaining (CR) Knee Replacement System (KRS) which is a standardized knee replacement system.

The subject Cruciate Sacrificing (CS) Insert has identical articular surfaces, design rules and features as the

primary predicate iTotal™ Identity™ Cruciate Sacrificing (CS) Insert. The different between the two inserts is that the subject insert is being standardized for use with the Identity™ Imprint™ Cruciate Retaining (CR) Knee Replacement System (KRS).

The Identity™ Imprint™ Cruciate Retaining (CR) Knee Replacement System (KRS) with Cruciate Sacrificing (CS) Insert, subject device single-use, disposable patient-specific instrumentation, implants, and reusable instruments remain identical to the secondary predicate device in operating principle, fundamental technology, design, and materials. The subject device uses the same packaging materials and sterilization methods as those of the predicate device. The manual and automated manufacturing methods remain the same as the predicate.

Non-Clinical Performance Evaluation:
The following testing was performed:

- Virtual Range of Motion (ASTM F2083)
- Verification/Validation Bioskills Lab

Conclusion:
Based on a comparison of the intended use and technological characteristics of the subject devices to predicate devices, and the results of the confirmatory testing, it is concluded that the proposed Identity™ Imprint™ Cruciate Retaining (CR) Knee Replacement System (KRS) with Cruciate Sacrificing (CS) Insert is considered substantially equivalent.