September 8, 2023

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

Re: K232426
Trade/Device Name: Identity™ Imprint™ Porous Cruciate Retaining (CR) Knee Replacement System (KRS) with Cruciate Sacrificing (CS) Inserts
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee Joint Patellofemorotibial Metal/Polymer Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: MBH, JWH, OIY, OOG
Dated: August 10, 2023
Received: August 11, 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,

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.

Submission Number *(if known)*

K232426

Device Name

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

Indications for Use *(Describe)*

The Identity™ Imprint™ Porous Cruciate Retaining (CR) Total Knee Replacement System with Cruciate Sacrificing (CS) Insert 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

The IIdentity™ Imprint™ Porous Cruciate Retaining (CR) Knee Replacement System (KRS) with Cruciate Sacrificing (CS) Insert is intended for uncemented use, but porous implants may be used with cement if desired by the surgeon.

The CS (cruciate sacrificing) 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.

Special 510(k) Summary

501(k) Number:	K232426
Submitter's Name and Address:	Conformis, Inc. 600 Technology Park Drive, Fourth Floor Billerica, MA 01821 USA
Main Telephone Number:	781-345-9164
Establishment Registration Number(s):	3009844603 and 3004153240
Date Summary was Prepared:	August 10, 2023
Contact Person:	Mary Kruitwagen Sr. Regulatory Affairs Specialist
Contact Information:	Mary.Kruitwagen@conformis.com 781-345-9038
Subject Device: Trade/Device Name(s):	Identity™ Imprint™ Porous Cruciate Retaining (CR) Knee Replacement System (KRS) with Cruciate Sacrificing (CS) Insert
Common Name:	Knee Replacement System
Type of Submission:	Special 510(k)
Device Class:	Class II
Regulation Number(s):	21 CFR 888.3565 - Knee joint patellofemorotibial metal/ polymer porous-coated uncemented prosthesis 21 CFR 888.3560 - Knee joint patellofemorotibial polymer/ metal/polymer semiconstrained cemented prosthesis
Product Codes:	• **MBH**: Knee Joint, Patellofemorotibial, Metal/Polymer porous coated uncemented prothesis • **JWH**: Knee joint patellofemorotibial polymer/metal/polymer semiconstrained cemented prosthesis • **OIY**: Prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer + additive/metal/polymer + additive • **OOG**: Knee Arthroplasty Implantation System
Classification Panel:	Orthopedics
Manufacturing Site:	Conformis Inc. 600 Research Drive Wilmington, Ma. 01887 USA

Primary Predicate Device:	Identity™ Imprint™ Porous Total Knee Replacement System, Identity Imprint Porous Cruciate Retaining Total Knee Replacement System
Primary Predicate 510(k):	K223316
Primary Predicate Regulation Number(s)	21 CFR 888.3565, 21 CFR 888.3560
Primary Predicate Classification Names and Product Codes:	• **MBH**: Knee Joint, Patellofemorotibial, Metal/Polymer porous coated uncemented prothesis • **JWH**: Knee joint patellofemorotibial polymer/metal/polymer semiconstrained cemented prosthesis • **OIY**: Prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer + additive/metal/polymer + additive • **OOG**: Knee Arthroplasty Implantation System
Secondary Predicate Device:	Identity™ Imprint™ Cruciate Retaining (CR) Knee Replacement System with CS insert
Second Predicate 510(k):	K230844
Reference Predicate Regulation Number(s)	21 CFR 888.3560
Reference Predicate Classification Names and Product Codes:	• **JWH**: Knee joint patellofemorotibial polymer/metal/polymer semiconstrained cemented prosthesis • **OIY**: Prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer + additive/metal/polymer + additive • **OOG**: Knee Arthroplasty Implantation System
Third Predicate Device:	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)
Third Predicate 510(k):	K230846
Third Predicate Regulation Number(s)	21 CFR 888.3560
Third Predicate Classification Names and Product Codes:	• **JWH**: Knee joint patellofemorotibial polymer/metal/polymer semiconstrained cemented prosthesis • **OIY**: Prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer + additive/metal/polymer + additive • **OOG**: Knee Arthroplasty Implantation System

Device Description:

The subject device, Identity™ Imprint™ Porous Cruciate Retaining (CR) Knee Replacement System (KRS) with Cruciate Sacrificing (CS) Insert, is proposed to be a modification from Identity™ Imprint™ Porous Total Knee Replacement System, Identity Imprint Porous Cruciate Retaining Total Knee Replacement System (K223316) to be compatible with the Identity™ Imprint™ Cruciate Sacrificing (CS) Tibial Insert cleared in K230844. This submission also seeks the inclusion of the cleared AIM2Surf software (K230846) for use with the subject device. This software is used by CAD to do preliminary surface planning. No software version change is required as the surface planning is unchanged between the predicate and subject devices. The Porous Ancillary Reusable instrument tray was modified and clearance of the modification is also sought.

The subject device, Identity™ Imprint™ Porous Cruciate Retaining (CR) Knee Replacement System (KRS) with Cruciate Sacrficing (CS) Insert, is a knee replacement system including standardized implant sizes

combined with standard and patient-specific ancillary surgical instrumentation. It 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 (CT scan), an Identity Imprint Porous implant is selected that best meets the geometric and anatomic requirements of the specific patient. The femoral component is manufactured from a cobalt chromium molybdenum (CoCrMo) alloy with a porous Commercially Pure titanium (CPTi) scaffold on the interior surface. The tibial tray is manufactured from a titanium alloy (Ti6Al4V-ELI), with a CPTi porous scaffold on the interior surface. The tibial insert component is manufactured from highly cross-linked ultra-high molecular weight Vitamin-E enriched polyethylene (iPoly XE). The patellar component is manufactured and offered in ultra-high molecular weight polyethylene (iPoly) with a solid titanium alloy (Ti6Al4V-ELI) and CPTi porous metal backing. Porous tibial, femoral, and patellar implants are designed for use without cement, but may be used with a cemented technique if necessary. The Identity™ Imprint™ Porous Knee Replacement System is compatible with cemented Identity™ Imprint™ CR KRS implants. Cemented and uncemented implants may be used together for a hybrid technique. The subject CS (cruciate sacrificing) insert option should be utilized when additional anterior-posterior constraint is desired.

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. These guides are pre-navigated to fit the contours of the patient's femoral and tibial anatomies and to facilitate a simpler surgical technique. The iJig instrument set is designed for single-use, and manufactured from biocompatible nylon material and supplied sterile along with the implants. In addition, reusable orthopedic manual surgical instruments are provided separately.

The device is intended to be used in a sterile field by trained orthopedic surgeons (Use Environment).

The Cruciate Sacrificing tibial insert of iPoly™ XE is offered in thicknesses of 6mm to 18mm and is the same insert as cleared with Identity™ Imprint™ Cruciate Retaining (CR) Knee Replacement System (KRS) with CS insert (K230844).

Indications for Use:
The Identity™ Imprint™ Porous Cruciate Retaining (CR) Knee Replacement System (KRS) with Cruciate Sacrificing (CS) Insert 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

The Identity™ Imprint™ Porous Cruciate Retaining (CR) Knee Replacement System (KRS) with Cruciate Sacrificing (CS) Insert is intended for uncemented use, but porous implants may be used with cement if desired by the surgeon.

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

Technological Characteristics:
The focus of this submission is to claim compatibility of the cleared of Cruciate Sacrificing tibial insert with Identity™ Imprint™ Porous Cruciate Retaining (CR) Knee Replacement System (KRS)(K223316). There is no change to either the Cruciate Sacrificing Tibial Insert (K230844) or the Identity™ Imprint™ Porous Cruciate Retaining (CR) Knee Replacement System (KRS) (K223316). Micromotion testing was performed to confirm that the CS insert can function as intended.

The subject device proposes the use of the 1.0 version of the AIM2Surf software cleared in K230846, which does preliminary bone surface planning, for use with the subject Identity™ Imprint™ Porous Cruciate Retaining (CR) Knee Replacement System (KRS). No version change is need as there is no difference in the surface planning. No software is necessary for the CS insert, however the AIM2Surf is seeking clearance with this submission for the subject Identity™ Imprint™ Porous Cruciate Retaining (CR) Knee Replacement System (KRS) with Cruciate Sacrificing (CS) Insert.

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

- Tibial Micromotion Testing

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