July 21, 2023

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

Re: K223316
Trade/Device Name: Identity Imprint Porous Total Knee Replacement System, Identity Imprint Porous Cruciate Retaining Total Knee Replacement System
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: October 19, 2022
Received: October 28, 2022

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.

510(k) Number *(if known)*
K223316

Device Name
Identity Imprint Porous Total Knee Replacement System,
Identity Imprint Porous Cruciate Retaining Total Knee Replacement System

Indications for Use *(Describe)*

The Identity Imprint Porous 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.

The Identity Imprint Porous Cruciate Retaining Total Knee Replacement System is intended for uncemented use, but porous implants may be used with cement if desired by the surgeon.

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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Traditional 510(k) Summary

510(k) Number	_K223316_____
Submitter's Name and Address:	Conformis, Inc. 600 Technology Park Drive, Fourth Floor Billerica, Massachusetts 01821 USA
Main Telephone Number Main	781-345-9164
Fax Number Establishment	781-345-0147
Registration Numbers(s):	3009844603 and 3004153240
Date of Summary Preparation	October 19, 2022; updated November 30, 2022
Contact Name:	Mary Kruitwagen
Title:	Sr. Regulatory Affairs Specialist
Contact Telephone:	781-345-9038
Contact email:	Mary.Kruitwagen@conformis.com
Alternate Contact:	Liz Haines
Title:	Vice President of Regulatory Affairs
Alternate Contact Telephone:	(978) 569-6862
Alternate Contact email:	Elizabeth.Haines@conformis.com
Subject Device: (Proprietary/ Trade Name)	Identity Imprint Porous Total Knee Replacement System, Identity Imprint Porous Cruciate Retaining Total Knee Replacement System
Common Usual Name	Knee Replacement System
Type of Submission	Traditional 510(k)
Device 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 Code(s)	**MBH**: prosthesis, knee, patello/femorotibial, semi-constrained, uncemented, porous, coated, polymer/metal/ polymer **JWH**: prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer **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
Establishment Registration	3004153240
Sterilization Site	Isomedix Operations Inc. Steris Isomedix Services 3459 South Clinton Ave. S. Plainfield, NJ 07080 USA
Establishment Registration	2246552
Primary Predicate Device:	Arthrex iBalance® TKA System
Primary Predicate Device 510(k):	K141635, September 3, 2014
Primary Predicate Device Product Code(s):	**MBH**: prosthesis, knee, patello/femorotibial, semi-constrained, uncemented, porous, coated, polymer/metal/polymer **JWH**: prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer
Secondary Predicate Device:	Identity Imprint Knee Replacement System Identity Imprint CR Knee Replacement System
Secondary Predicate Device 510(k):	K221404
Secondary Predicate Device Product Codes:	**JWH**: prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer **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 Total Knee Replacement System (including Identity Imprint Porous Cruciate Retaining Total Knee Replacement System) is a knee replacement system including standardized implant sizes combined with standard and patient-specific ancillary surgical instrumentation. As with other Conformis Knee Replacement Systems (KRS), the Identity Imprint Porous Knee Replacement System (KRS) 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. The device is intended for cementless fixation however the surgeon may also use cement.

Using patient imaging (CT scans), an Identity Imprint set of implants is selected. The femoral component is manufactured from a cobalt chromium molybdenum (CoCrMo) alloy with a porous Commercially Pure

titanium (CP Ti) scaffold on the interior surface. The tibial tray is manufactured from a titanium alloy (Ti6Al4V-ELI), with a CP Ti 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. The layer of CPTi scaffolding bonded to the femoral, tibial, and patellar implants provides a surface for porous ingrowth, promoting biological fixation and obviating the need for bone cement to achieve fixation. Porous tibial, femoral, and patellar implants are designed for use without cement, but may be used with a cemented technique if necessary.

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 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 Indications for Use:
The Identity Imprint Porous 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

The Identity Imprint Porous Cruciate Retaining Total Knee Replacement System is intended for uncemented use, but porous implants may be used with cement if desired by the surgeon.

Technological Characteristics:
The subject device single-use, disposable patient-specific instrumentation, implants, and reusable instruments are similar to the predicate device in operating principle, fundamental technology, design, and materials. The subject device implants use the same materials as the predicate Identity Imprint CR

KRS device, with a porous coating on the bone cut sides of the femoral and tibial implants. The patellar component also has a porous coating on metal backing. The coating is the same as used in the predicate Arthrex iBalance® TKA device. The fixation method of the subject device is for cementless application, although the surgeon may use cement if desired. 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 or similar to the predicate Identity Imprint CR KRS.

The focus of this submission is to seek clearance for a porous version of the Identity Imprint Porous Total Knee Replacement System along with hybrid combinations of the cemented implants in K221404.

Non-Clinical Performance Evaluation:
There is no change to the articulating surfaces, UHMWPe inserts or interlocks compared to the predicate Identity Imprint CR KRS device. The testing performed and included in this submission is relative to the areas of change from the - predicate Identity Imprint CR KRS device. The following confirmatory testing was performed:

- Femoral and Tibial Fatigue testing
- Patella Shear Testing
- Patella Tensile Testing
- Porous Bond Shear and Tensile Strength
- Tibial Micromotion
- Patella Durability/Wear Thru Testing
- MRI Compatibility Testing
- Cadaveric Testing

The subject device verification and validation data provided in this submission supports that the subject device is as safe, effective, and performs as well as or better than the predicate device. No different issues of safety or effectiveness were raised.

Conclusion:
Based on a comparison of the intended use and technological characteristics to the predicate devices and on the results of confirmatory testing, it is concluded that the proposed Identity Imprint Porous Total Knee Replacement System is substantially equivalent to the predicate devices.