



May 26, 2023

Conformis, Inc.
Nivedita Namjoshi
Project Manager, Regulatory Affairs
600 Technology Park Drive
Billerica, Massachusetts 01821

Re: K231233

Trade/Device Name: Identity™ Imprint™ CR KRS and Identity™ Imprint™ PS KRS

Regulation Number: 21 CFR 888.3560

Regulation Name: Knee Joint Patellofemoral Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis

Regulatory Class: Class II

Product Code: JWH, OIY, OOG

Dated: April 28, 2023

Received: April 28, 2023

Dear Nivedita Namjoshi:

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

Indications for Use

Submission Number (if known)

K231233

Device Name

Identity™ Imprint™ CR KRS and Identity™ Imprint™ PS KRS

Indications for Use (Describe)

Identity Imprint CR KRS

The Identity Imprint CR 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 unicompartmental, patellofemoral or bicompartamental 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 unicompartmental, patellofemoral or bicompartamental 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 PS KRS

The Identity Imprint PS 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 unicompartmental, patellofemoral or bicompartamental prosthesis.

The Indications for Use include:

- Painful joint disease due to osteoarthritis, traumatic arthritis, rheumatoid arthritis, polyarthritis or osteonecrosis of the knee.
- Post traumatic loss of joint function
- Moderate varus, valgus or flexion deformity
- Failed osteotomies, hemiarthroplasties, and unicompartmental, patellofemoral or bicompartamental implants
- Revision procedures provided that the 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.

510(k) SUMMARY

Submitter's Name and Address: Conformis, Inc.
600 Technology Park Drive, 4th Floor
Billerica, MA 01821

Establishment Registration Number(s): 3009844603 and 3004153240

Date Summary was Prepared: April 28, 2023

Contact Person: Nivedita Namjoshi
Project Manager, Regulatory Affairs
Nivedita.namjoshi@conformis.com
(781) 374-5604

Trade/Device Name(s):
Identity™ Imprint™ CR KRS and Identity™ Imprint™ PS KRS

Common Name:
Knee Replacement System

Device Class:
Class II

Regulation Number:
888.3560

Classification Name:
Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis.

Product Codes: JWH, OIY, OOG

Legally Marketed Predicate Devices (Primary & Secondary Predicate):
Identity Imprint CR & PS KRS (K221404)

iTotal Identity Cruciate Retaining (CR) Knee Replacement System, iTotal Identity Posterior Stabilizing (PS) Knee Replacement System (K210152)

Device Description:

The Conformis Identity™ Imprint™ CR KRS and Identity™ Imprint™ PS KRS hereafter referred as Identity Imprint KRS Knee Replacement System (KRS) represents a family of standardized Posterior Stabilized (PS) knee implants, Cruciate Retaining (CR) knee implants, and compatible system component product offerings based on the Identity Imprint PS and CR knee replacement systems. The total knee replacement system for each size includes a femoral implant, tibial tray, polyethylene inserts, patient-specific and standardized iJigs, as well as surgical instrumentation. The system also includes an iView, generated utilizing Conformis' 'Best Fit' planning software. The products are intended for treatment of severe pain and/or disability of the knee damaged by osteoarthritis or trauma.

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.

Indications for Use:

Identity Imprint CR KRS

The Identity Imprint CR 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 unicondylar, patellofemoral or bicompartamental 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 bicompartamental 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 PS KRS

The Identity Imprint PS 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 unicondylar, patellofemoral or bicompartamental prosthesis.

The Indications for Use include:

- Painful joint disease due to osteoarthritis, traumatic arthritis, rheumatoid arthritis, polyarthritis or osteonecrosis of the knee.
 - Post traumatic loss of joint function
 - Moderate varus, valgus or flexion deformity
 - Failed osteotomies, hemiarthroplasties, and unicondylar, patellofemoral or bicompartamental implants
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- Revision procedures provided that the anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

This implant is intended for cemented use only.

Technological Characteristics:

The device single-use, disposable patient-specific instrumentation, implants, and reusable instruments remain identical to the 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. This submission seeks clearance of VHP-LTS-V as an alternative sterilization method for disposable surgical instruments (iJigs). This submission seeks clearance of extended shelf life for the standardized iJigs to 2.75 years and Tibial Inserts to 5 years.

Non-Clinical Performance Evaluation:

This change does not impact device design, function or intended use. This submission seeks clearance of VHP-LTS-V as an alternative sterilization method for disposable surgical instruments (iJigs). This submission also seeks clearance of extended shelf life for the standardized iJigs to 2.75 years and Tibial Inserts to 5 years. Applicable documentation, including sterilization, shelf life, and package integrity validation testing was provided to support these changes.

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 KRS is substantially equivalent to the predicate devices.
