



September 23, 2021

Conformis Inc.  
Kara Johnson  
Sr. Director, Regulatory Affairs  
600 Technology Park Drive, 4th Floor  
Billerica, Massachusetts 01821

Re: K212411

Trade/Device Name: Identity Imprint Knee Replacement System (including Identity Imprint Posterior Stabilized (PS) KRS and Identity Imprint Cruciate Retaining (CR) 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: August 2, 2021

Received: August 3, 2021

Dear Kara Johnson:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ting Song, Ph.D., R.A.C.  
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: 06/30/2020  
See PRA Statement below.

510(k) Number (if known)

K212411

Device Name

Identity Imprint Knee Replacement System (including Identity Imprint Posterior Stabilized (PS) KRS and Identity Imprint Cruciate Retaining (CR) KRS)

Indications for Use (Describe)

The Identity Imprint 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 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 of flexion deformity.
- 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.

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."*

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

**Establishment Registration Number(s):** 3009844603 and 3004153240

**Date Summary was Prepared:** July 30, 2021

**Contact Person:** Kara Johnson  
Sr. Director, Regulatory Affairs  
Telephone: 781-832-5402  
Email: [kara.johnson@conformis.com](mailto:kara.johnson@conformis.com)

**Trade/Device Name(s):**  
Identity Imprint Knee Replacement System (including Identity Imprint Posterior Stabilized (PS) KRS and Identity Imprint Cruciate Retaining (CR) KRS)

**Common Name:**  
Knee Replacement System

**Device Class:**  
Class II

**Regulation Numbers:**  
888.3560

**Classification Names and Product Codes:**  
Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/PolymerKnee Arthroplasty Implantation System; JWH, OIY, OOG

**Legally Marketed Predicate Devices**

**(Primary Predicate):**

Identity Imprint Knee Replacement System (K210191)

**(Secondary Predicates):**

iTotal Identity Cruciate Retaining (CR) Knee Replacement System (K190562)

iTotal Identity Posterior Stabilized (PS) Knee Replacement System (K201023)

**Device Description:**

The subject device, Identity Imprint Knee Replacement System, 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.

#### **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 bicompartental 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.

**Technological Characteristics:**

The subject 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 manufacturing methods remain the same as the predicate. The focus of this submission is on manufacturing software enhancements aimed at adding an option to use an automated process in lieu of the previously cleared manual processes in order to improve manufacturing efficiencies.

**Non-Clinical Performance Evaluation:**

The following confirmatory testing was performed:

- Software Verification and Validation

The software verification and validation data provided in this submission supports that the subject device is safe, effective, and performs as well as or better than the predicate device. No new issues of safety or efficacy 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 KRS is substantially equivalent.