May 6, 2021

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

Re: K210191
Trade/Device Name: Identity Imprint Knee Replacement System
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: April 16, 2021
Received: April 19, 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) 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)*
K210191

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 bicompartmental 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 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.

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.

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510(k) SUMMARY

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:	January 21, 2021
Contact Person:	Kara Johnson Director, Regulatory Affairs Telephone: 781-832-5402 Email: kara.johnson@conformis.com

Trade/Device Name(s):
Identity Imprint Knee Replacement System

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 Device

(Primary Predicate):
iTotal Identity Cruciate Retaining (CR) Knee Replacement System (K190562)

(Secondary Predicates):
iTotal Identity Posterior Stabilized (PS) Knee Replacement System (K201023)
iTotal CR & PS KRS – addition of iPoly XE NMA GUR 1020E (K203447)

Device Description:
The subject device, Identity Imprint Knee Replacement System, is a new device offering of 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 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.

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 bicompartmental 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 devices incorporate updates to the material and design which are consistent with previously cleared devices. The operating principle, fundamental technology, manufacturing methods and sterilization options are the same as the predicates.

The single-use, disposable patient-specific instrumentation design processes for the subject device are similar to those employed for the predicate devices. The implants and instrumentation serve the same function and employ the same technological characteristics as those of the predicate devices. The subject device components are composed of the same materials, respectively, as the predicate devices. The subject device uses the same packaging materials and sterilization methods as those of the predicate devices.

Non-Clinical Performance Evaluation:

The following confirmatory testing was performed:

- Cadaver/bioskills lab
- Femoral implant fatigue test
- implant range of motion evaluation

The assessment of the non-clinical data provided in this submission supports that the subject device is safe, effective, and performs as well as or better than the predicate device(s). 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.