May 23, 2023

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

Re: K231178
Trade/Device Name: Actera™ hip system
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip Joint Metal/Ceramic/Polymer Semi-Constrained Cemented Or Nonporous Uncemented Prosthesis
Regulatory Class: Class II
Product Code: MEH, OQG
Dated: April 24, 2023
Received: April 26, 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,

Limin Sun -S

Limin Sun, 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)*
K231178

Device Name

ACTERA™ hip system

Indications for Use *(Describe)*

The ACTERA™ hip system may be designed from a patient's preoperative CT scan which must include certain necessary anatomic landmarks that are clearly identifiable. Total hip replacement using the ACTERA™ hip system is indicated for use in skeletally mature individuals undergoing total hip replacement due to:

- A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis, or congenital hip dysplasia.
- Treatment of non-displaced non-unions of the hip, femoral neck fractures, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques.
- Revision procedures for failed previous hip surgery (excluding situations where hardware is present).

The ACTERA™ hip system implants are intended for cementless fixation using an anterior, lateral or posterior surgical technique.

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, Fourth Floor Billerica, MA 01821 USA
Establishment Registration Number(s):	3009844603 and 3004153240
Date Summary was Prepared:	May 15, 2023
Contact Person: **Contact Information:**	Mary Kruitwagen Sr. Regulatory Affairs Specialist Mary.Kruitwagen@conformis.com 781-345-9038
Trade/Device Name(s) Device 1 **Common Name:** **Device Class:**	ACTERA™ hip system Total Hip Replacement System Class 2
Regulation Number(s) and Classification Names	21 CFR 888.3353 - Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis 21 CFR 888.3358 - Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Product Codes:	Prosthesis, hip, semi-constrained, uncemented, metal / polymer, non-porous, calcium phosphate (MEH) Hip Prosthesis, Semi-Constrained, Cemented, Metal/Polymer, + Additive, Porous, Uncemented (OQG)
Primary Predicate Device:	K221104 Actera Hip System
Secondary Predicate Device:	K192198 Conformis Hip System (Rebranded Cordera HipRx)

Device Description:

The ACTERA™ hip system is an uncemented, primary total hip replacement system comprised of femoral and acetabular components. All implanted components are provided sterile. Optional Surgical plans (iViews) and iJigs/ancillary instruments are also available. Non-sterile reusable instruments are provided.

The subject ACTERA™ is comprised of the subject Actera™ femoral stem (cleared in K221104) with additional sizes (0, 1 and 10, 11, 12) added to the size portfolio. Additionally, the subject ACTERA™ will offer a patient specific neck option. This option has the same stem body (K221104) with a patient specific neck (K192198). The patient specific neck has the same neck version angle, neck angle, and similar neck length as that cleared in the secondary predicate Conformis Hip System (K192198). The subject hip stems with patient specific necks are compatible with the same femoral heads and acetabular components as the patient specific necks cleared in the Conformis Hip System (K192198). The ACTERA™ with the patient-specific neck option will be ordered as 'ACTERA™ HipRx'.

This submission also seeks clearance of iJigs®/Ancillary Instruments to assist in the positioning of the ACTERA™ implants. The iJigs® are sterile, single-use disposable instruments of nylon material. These instruments may be standardized or patient specific. These instruments are the same as the iJig instrumentation described in the secondary predicate K192198 (and K202484). These instruments were not offered with the initial release of the ACTERA™ device, primary predicate Actera™ K221104. Additionally, Surgical Plans, called iViews, are also part of this submission. The iJigs and iViews are provided based on ordered options.

The stem taper is identical to the predicates. The subject device, ACTERA™ is compatible with the previously cleared femoral heads (Ceramic or CoCrMo) and acetabular components. The femoral head is unchanged from the previously cleared predicate Conformis Cordera Hip system (K202484). The Cordera acetabular cup, Cordera cup liner and Cordera screws are unchanged from the previously cleared predicate Conformis Cordera Hip system (K202484). There are no changes with this these components and are not the subject of this submission.

The purpose of this submission is to seek clearance of the subject ACTERA™ femoral stems (expanded sizes and patient specific neck option), iJigs and surgical plans, which are substantially equivalent to the cleared primary and secondary predicate devices.

Indications for Use:

The ACTERA™ hip system may be designed from a patient's preoperative CT scan which must include certain necessary anatomic landmarks that are clearly identifiable. Total hip replacement using the ACTERA™ hip system is indicated for use in skeletally mature individuals undergoing total hip replacement due to:

- A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis, or congenital hip dysplasia.
- Treatment of non-displaced non-unions of the hip, femoral neck fractures, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques.
- Revision procedures for failed previous hip surgery (excluding situations where hardware is present).

The ACTERA™ hip system implants are intended for cementless fixation using an anterior, lateral or posterior surgical technique.

Technological Characteristics:

The subject ACTERA™ femoral stem extends the size portfolio to 0-12 and the ACTERA™ HipRx is the previously cleared ACTERA stem body with a patient specific neck. Both stems are compatible with the previously cleared femoral heads and acetabular components. The iJigs are similar to those of the

secondary predicate device. The subject devices incorporate components with materials and designs that are the same as the previously cleared predicate devices. The operating principle, fundamental technology, materials, manufacturing methods and sterilization options are the same as the primary predicate device.

Non-Clinical Performance Evaluation:
The ACTERA™ femoral stem (with extended sizes and with the patient specific neck option), iView and iJigs are introduced in this submission. Performance testing includes ISO 7206-6 stem neck fatigue testing and ISO 7206-4 distal stem fatigue testing. Tensile Testing, Static Shear Stress Testing, Shear Fatigue Testing and coating microstructure characterization were previously performed. Verification and validation studies were also conducted. The results of the testing support that the subject device is as safe and as effective as the predicate devices. No new issues of safety or efficacy were raised.

Conclusion:
Based on a comparison of the intended use and technological characteristics of the subject devices to predicate devices, and the results of the confirmatory testing, it is concluded that the proposed ACTERA™ hips system is considered substantially equivalent.