August 4, 2022

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

Re: K221104
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: May 24, 2022
Received: May 25, 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,

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)*
K221104

Device Name
Actera™ hip system

Indications for Use *(Describe)*
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:	July 19, 2022
Contact Person: **Contact Information:**	Mary Kruitwagen Sr. Regulatory Affairs Specialist Mary.Kruitwagen@conformis.com 781-345-9038
Trade/Device Name(s) **Common Name:** **Device Class:** **Regulation Number(s) and Classification Names**	Actera™ hip system Total Hip Replacement System Class 2 21 CFR 888.3353, Hip Joint Metal/Ceramic/Polymer Semi-Constrained Cemented Or Nonporous Uncemented Prosthesis 21 CFR 888.3358, Hip joint metal/polymer/metal semi-constrained porous-coated 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:	K210581 DePuy Orthopaedic Inc. ACTIS® Duofix Hip Prothesis
Reference Device:	K202484 Conformis Cordera Hip System

Device Description:

The Actera™ hip system is an uncemented, total hip replacement system comprised of femoral and acetabular components. All implanted components are provided sterile. X-ray templates, acetate or digital, are provided for determining implant sizes and component placement. Non-sterile reusable instruments are provided. The subject Actera™ hip system is comprised of the subject Actera™ femoral

stem and the previously cleared compatible femoral head, Cordera acetabular cup, Cordera cup liner and Cordera screws (predicate K202484).

The subject, Actera™ femoral stem, is a re-designed stem. The stem is a proximally filling, triple-tapered design that is substantially equivalent to the cleared predicate device DEPUY ACTIS® Hip Stem (K210581).

The femoral stem has an integrated neck with neck angle of 132° and neck length that progressively increases with stem size. Each size has two neck options: a standard neck, and a high offset neck that is shifted medially to provide additional femoral offset with the same leg length. The trunnion is a Conformis standard 12/14 taper, possessing a 12.7 mm diameter along with 5° 42' 30" angle with an as-machined geometry to form a taper lock with a mating femoral head implant. The trunnion is identical to that of the predicate Conformis Cordera femoral stem. The trunnion is designed to mate with existing standard 12/14 femoral heads. The stem body has a smooth tapered geometry in three planes. The proximal neck surface of the stem is highly polished; its geometry is intended to maximize range of motion. The femoral stems are designed to maximize contact between the stem and cancellous bone of the intramedullary canal and utilize press-fit fixation. The stem body is fully coated with hydroxyapatite (HA) coating in conformance to ASTM F1185 on top of a proximal coating of commercially pure titanium (CPTi) conforming to ASTM F1580.

The femoral heads are unchanged from the previously cleared reference device Conformis Cordera Hip system (K202484). The femoral heads are available in either cobalt chromium alloy (CoCr) or ceramic (BIOLOX® *delta*). The femoral heads are designed to connect to the femoral stem neck. All femoral heads are polished and have a 12/14 taper to match the femoral stem.

The acetabular component is unchanged from the previously cleared reference device Conformis Cordera Hip system (K202484). It consists of a standard size shell in 1mm increments with standard screw hole placement, a mating vitamin E polyethylene liner, and cancellous screws. The acetabular component is designed for uncemented use; initial implant fixation is achieved through press-fit design. The 6.5mm diameter cancellous screws with low profile head fit through the acetabular shell screw holes and are driven using a 3.5mm hex drive recess. The acetabular component has matching circumferential scallops on the shell and liner that rotationally secure the liner in the shell and allow for dialing the liner in a desired orientation.

The purpose of this submission is to seek clearance of the subject Actera™ femoral stem which is substantially equivalent to the cleared predicate device DEPUY ACTIS® Hip Stem (K210581). The subject Actera femoral stem is compatible with the previously cleared femoral head, Cordera acetabular cup and liner, Cordera screws and reusable instruments (class II and Class I) as described in the predicate K210581. . This submission also seeks clearance for new class II reusable instruments. New class I 510K-exempt reusable instruments and x-ray templates are also described.

Indications for Use:

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.

Indications and Technological Characteristics Comparison:
The indications for use in total hip replacement are similar to the primary predicate. The subject indications for use differ from the primary predicate because the subject system is not indicated for use in hemi-hip replacement. However, the subject device indications for use are almost identical to the reference device total hip replacement system and only differ through modification to include the lateral approach. The subject device incorporates total hip arthroplasty components with materials and designs that are the similar to the DePuy Orthopaedics ACTIS® DuoFix Hip Prothesis, K210581 predicate. The operating principle, fundamental technology, materials, manufacturing methods and sterilization options are the same as the predicate.

Non-Clinical Performance Evaluation:
Performance testing includes proximal stem fatigue testing (ISO 7206-6), distal stem fatigue testing (ISO 7206-4), range of motion analysis per ISO 21535, impingement analysis, and coating characterization testing (ASTM F1854 stereological porous coating evaluation, ASTM F1147 static tensile testing, ASTM F1044 static shear testing, ASTM F1160 shear and bending fatigue testing, ASTM F1978 Taber abrasion testing, ASTM F1926 dissolution rate testing, ASTM F2024 phase composition testing per X-ray diffraction, and Ca/P ratio characterization testing using XRD analysis or wet chemistry method). Limulus Amebocyte Lysate (LAL) testing using the gel-clot method is employed to monitor the endotoxin levels of the subject and predicate implanted device and ensures they are within the recommended levels of 0.5 EU/mL or 20 EU/device. Verification and validation studies were also conducted. The results of the testing support 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 of the subject device to predicate, and the results of the confirmatory testing, it is concluded that the proposed Actera™ hip system is considered substantially equivalent.