Conformis, Inc.
Nancy Giezen
Manager Regulatory Affairs
600 Technology Park Drive
Billerica, Massachusetts 01821

September 24, 2020

Re: K202484
Trade/Device Name: Cordera Hip System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip Joint Metal/Polymer/Metal Semi-Constrained Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LPH, LZO, OQG, MEH
Dated: August 26, 2020
Received: August 31, 2020

Dear Nancy Giezen:

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,

Vesa Vuniqi,
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)*
K202484

Device Name
Cordera Hip System

Indications for Use *(Describe)*
The Cordera™ Hip System may be used with iJigs® designed from a patient's pre-operative CT scan, which must include certain necessary anatomic landmarks that are clearly identifiable. The Cordera™ 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 Cordera™ Hip System includes standard hip replacement components, and if selected, may use patient-specific single use instrumentation.

The Conformis Cordera Hip System implants are intended for cementless fixation using an anterior or posterior surgical approach.

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: August 25th, 2020

Contact Person: Nancy Giezen
Manager Regulatory Affairs
Telephone: 781-345-9058

Trade/Device Name(s):
Conformis Hip System

Common Name:
Hip Replacement System

Device Class:
Class II

Regulation Numbers:
21 CFR 888.3353, 21 CFR 888.3358

Classification Names and Product Codes:
Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (LZO, MEH)
Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis (LPH, OQG)

Legally Marketed Predicate Device
(Primary Predicate):
BeneFIT Hip System (K190904)

(Secondary Predicates):
Conformis Hip System (K162719, K192198)

Device Description:
The Cordera Hip System is an uncemented, primary total hip replacement composed of femoral and acetabular components. The system can be used with or without a pre-operative CT scan that is used to design patient-specific instruments. All components are provided sterile.

The femoral component consists of a standard monoblock femoral stem body and neck, which mates with a standard femoral head. The stem and neck are manufactured as one piece and hence are not modular. The proximal neck surface with a 12/14 taper is highly polished and transitions to hydroxyapatite coating in the main stem body and is indicated for uncemented press fit fixation only. The femoral head is 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 femoral heads are available in either cobalt chromium alloy (CoCr) or ceramic (Biolox® Delta).

The acetabular component consists of a standard size shell in 1mm increments with standard screw hole placement, a mating 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 liner is provided with an impactor made of a biocompatible nylon material.

The purpose of this submission is to add patient specific instruments (iJigs) and surgical plans (iViews) to the Cordera Hip System.

Indications for Use:
The Cordera™ Hip System may be used with iJigs® designed from a patient's pre-operative CT scan, which must include certain necessary anatomic landmarks that are clearly identifiable. The Cordera™ 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 Cordera™ Hip System includes standard hip replacement components, and if selected, may use patient-specific single use instrumentation.

The Conformis Cordera Hip System implants are intended for cementless fixation using an anterior or posterior surgical approach.

Technological Characteristics:
The subject devices incorporate components with materials and designs consistent with previously cleared devices. The operating principle, fundamental technology, manufacturing methods and sterilization options are the same as the predicates.

Non-Clinical Performance Evaluation:
No new Cordera implants were introduced in this submission. The patient specific iJigs are made using the same design criteria, from the same materials and use the same manufacturing methods as the predicate device. Process controls are in place to ensure that the iJigs meet the performance criteria and that the risks associated with design and development of the patient specific features are mitigated.

Conclusion:
Based on a comparison of the intended use and technological characteristics to predicate devices the Cordera Hip System is considered substantially equivalent to the predicates.