ConforMIS, Inc.
Emmanuel Nyakako
Sr. Vice President, Regulatory and Quality Affairs
600 Technology Park
Billerica, Massachusetts 01821

August 28, 2019

Re: K190904
Trade/Device Name: Conformis BeneFIT 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, MEH, OQG
Dated: July 29, 2019
Received: July 30, 2019

Dear Emmanuel Nyakako:

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,

FOR Vesa Vuniqi
Acting 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)*
K190904

Device Name
ConforMIS, Inc. BeneFIT Hip System

Indications for Use *(Describe)*
The ConforMIS BeneFIT 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, manageable by other techniques.
- Revision procedures for failed previous hip surgery (excluding situations where hardware is present).
  The ConforMIS BeneFIT 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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6.0 510(K) SUMMARY (PAGE 1 OF 5)

Submitter's Name and Address:	ConforMIS, Inc. 600 Technology Park Billerica, MA 01821
Establishment Registration Number:	3009844603 and 3004153240
Date of Summary:	July 29, 2019
Contact Person:	Emmanuel Nyakako, Sr. Vice President, Regulatory and Quality Affairs
Telephone Number:	(781) 345-9164
Fax Number:	(781) 583-5006
Name of the Device:	ConforMIS BeneFIT Hip System
Common Name:	Total Hip Replacement System
Regulatory Status and Regulation Number:	Class II 21 CFR 888.3358 21 CFR 888.3353
Classification Name:	Uncemented, primary total hip replacement composed of femoral and acetabular components.
Device Classification:	Product Code: LPH: Prosthesis, hip, semi-constrained, metal/polymer, porous uncemented LZO: Hip joint metal/ceramic/polymer semi constrained cemented or nonporous uncemented MEH: Prosthesis, hip, semi-constrained, uncemented, metal/polymer, non-porous, calcium phosphate OQG: Hip Prosthesis, semi-constrained, cemented, metal/polymer, + additive, porous, uncemented

510(K) SUMMARY (PAGE 2 OF 5)

Indications for Use:

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

Identification of the Legally Marketed Devices (Predicate Devices):

Primary Predicate:

Conformis iTotal Hip System
Device Class: II
Product Code: LPH, JDI, OQG, OQH
Regulation Number: 21 CFR 888.3358
510(k) Number: K162719

Secondary Predicates:

Corail AMT Hip Prosthesis
Device Class: II
Product Code: LZO
Regulation Number: 21 CFR 888.3353
510(k) Number: K042992

Exactech Novation Crown Cup with InteGrip Acetabular ShellDevice Class: II
Product Code:
Regulation Number: 21 CFR 888.3353
510(k) Number: K102795

510(K) SUMMARY (PAGE 3 OF 5)

Device Description:

The Conformis BeneFIT Hip System is an uncemented, primary total hip replacement composed of femoral and acetabular components. 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 fits through the acetabular shell screw holes and is 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.

510(K) SUMMARY (PAGE 4 OF 5)

Substantial Equivalence:

The Conformis BeneFIT Hip System, subject of this premarket notification is substantially equivalent to the Conformis iTotal Hip Replacement System (**K162719**, cleared June 14, 2017), the Corail AMT Hip Prosthesis (**K042992**, cleared February 11, 2005), and the Exactech Exactech Novation Crown Cup with InteGrip Acetabular ShellDevice (K102795, cleared February 2, 2011). Non-clinical testing was conducted in accordance with applicable FDA guidance documents to confirm that the Conformis BeneFIT Hip System is substantially equivalent to the predicate hip systems.

510(K) SUMMARY (PAGE 5 OF 5)

Description and Assessment of Nonclinical Testing:

Nonclinical Testing: The determination of substantial equivalence for this device was based on a detailed device description and non-clinical laboratory testing. Testing on the Conformis BeneFIT Hip System included functional testing in compliance with the applicable FDA guidance documents.

Specifically, the following tests were conducted to evaluate the performance of the device:

- Femoral Stem Fatigue Testing
- Femoral Neck Fatigue Testing
- Femoral Taper-CoCr head Junction Testing
- Femoral Taper-Ceramic Head Junction Testing
- Acetabular Liner-Cup Disassembly Testing
- Acetabular Liner Impingement Testing
- Wear Testing
- Acetabular Bone Screw Testing
- HA Coating Microstructure Characterization
- HA Coating Static Fatigue Testing
- HA Coating Shear Fatigue
- Range of Motion Testing
- Chemical and Mechanical Characterization of iPoly XE
- Cadaveric Evaluation
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Test results demonstrated that the device can be considered substantially equivalent to the predicate devices for the specified intended use.

Conclusion:

Based on the testing conducted, it is concluded that the Conformis BeneFIT Hip System is substantially equivalent to the predicate devices: Conformis iTotal Hip Replacement System (**K162719**, cleared June 14, 2017), the Corail AMT Hip Prosthesis (**K042992**, cleared February 11, 2005), and the Exactech Exactech Novation Crown Cup with InteGrip Acetabular ShellDevice (K102795, cleared February 2, 2011)