DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 14, 2017

ConforMIS, Inc.
Emmanuel Nyakako
Sr. Vice President, Regulatory And Quality Affairs
600 Technology Park Drive
Billerica, MA 01821

Re: K162719
Trade/Device Name: iTotal® Hip Replacement 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: May 15, 2017
Received: May 16, 2017

Dear Mr. 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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162719

Device Name
iTotal® Hip Replacement System

Indications for Use *(Describe)*
The iTotal® Hip Replacement System is designed from a patient's pre-operative CT scan which must include certain necessary anatomic landmarks that are clearly identifiable. Total hip replacement using the iTotal® Hip Replacement 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 iTotal® Hip Replacement System includes standard hip replacement components as well as the following patient specific components: femoral neck, acetabular cup, single use instrumentation.

The iTotal® Hip Replacement 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.

6.0 510(K) SUMMARY (PAGE 1 OF 5)

Submitter's Name and Address:	ConforMIS, Inc. 600 Technology Park Drive Billerica, MA 01821
Establishment Registration Number:	3009844603 and 3004153240
Date of Summary:	June 9, 2017
Contact Person:	Emmanuel O. Nyakako, Sr. Vice President, Regulatory and Quality Affairs
Telephone Number:	(781) 345-9164
Fax Number:	(781) 345-0147
Name of the Device:	iTotal® Hip Replacement System
Common Name:	Total Hip Replacement System
Regulatory Status and Regulation Number:	Class II 21 CFR 888.3358 21 CFR 888.3353
Classification Name:	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis and Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.
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 iTotal® Hip Replacement System is designed from a patient's pre-operative CT scan which must include certain necessary anatomic landmarks that are clearly identifiable. Total hip replacement using the iTotal® Hip Replacement 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 iTotal® Hip Replacement System includes standard hip replacement components as well as the following patient specific components: femoral neck, acetabular cup, single use instrumentation.

The iTotal® Hip Replacement implants are intended for cementless fixation using an anterior or posterior surgical approach.

Identification of the Legally Marketed Devices (Predicate Devices):

Pipeline Total Hip System
Device Class: II
Product Code: LPH, JDI, OQG, OQH
Regulation Number: 21 CFR 888.3358
510(k) Number: K112802

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

Signature Planner, Signature Guides
Device Class: II
Product Code: LPH, LZO, KWZ, JDI, KWY, MAY MEH
Regulation Number: 21 CFR 888.3358
510(k) Number: K111863

Identification of the Legally Marketed Devices (Reference Devices):

iTotal® CR & PS Knee Replacement Systems
Device Class: II
Product Code: JWH, OOG, OIY
Regulation Number: 21 CFR 888.3560
510(k) Number: K160025 & K161668

510(K) SUMMARY (PAGE 3 OF 5)

Device Description: The iTotal® Hip Replacement System is a patient specific hip replacement system which consists of femoral and acetabular components and patient specific instrumentation (iJigs). The femoral component consists of a standard femoral stem body with an integrated (non-modular) patient specific neck, which connects with a standard femoral head. The acetabular component consists of a metal acetabular cup with two screw holes and polyethylene liners in standard sizes. Standard bone screws and apex hole plug may also be provided with the iTotal® Hip Replacement System.

The iTotal® Hip Replacement System is intended to treat skeletally mature patients who are candidates for total hip replacement surgery.

Using patient imaging (CT scan) and a combination of proprietary and off the shelf software, a patient specific hip replacement system is designed. The iTotal® Hip Replacement System consists of the following components:

a) Femoral Component:
   - The femoral stem, with an integrated patient specific neck, is manufactured from titanium alloy and has a plasma sprayed hydroxyapatite (HA) coating. The femoral stem is available in various sizes.
   - Both metal (Cobalt Chromium alloy) and Ceramic femoral heads are available for use with the iTotal® Hip Replacement System. The femoral heads are available in various sizes and offsets.

b) Acetabular Component:
   - The acetabular cup is manufactured from titanium alloy. The acetabular cup features a plasma sprayed outer surface. The acetabular cups are available in various sizes.
   - The acetabular liner is manufactured from highly cross-linked Vitamin E infused ultra-high molecular weight polyethylene (iPoly® XE). The liners are available in a range of sizes with varying internal diameters and offsets.
   - Acetabular screws and the apex hole plug are manufactured from titanium alloy.

c) Ancillary orthopedic manual surgical instruments are provided with the iTotal® Hip Replacement system to assist with implantation. The ancillary instruments are provided sterile and for single-use only. These patient specific instruments are provided to assist in the positioning of total hip replacement components intra-operatively and in guiding the cutting/reaming of bone.

510(K) SUMMARY (PAGE 4 OF 5)

Summary of Technological Characteristics:

The rationale for substantial equivalence is based on consideration of the following device use and characteristics:

- Intended Use: Similar to the predicate devices, the proposed iTotal® Hip Replacement System is intended to be as a total hip prosthesis.
- Indications for Use: The proposed indications for use for the iTotal® Hip Replacement System are similar to the predicate devices as they have the same intended use.
- Operating Principle/Fundamental Technology: Similar to the predicate devices the proposed iTotal® Hip Replacement System is a semi-constrained, cementless artificial hip replacement system; it consists of a femoral stem with an integrated neck and a standard femoral head, an acetabular cup with polyethylene liner, with optional acetabular screws/apex holes plug, and ancillary instrumentation.
- Materials/Coatings: The proposed iTotal® Hip Replacement system uses the same biocompatible materials (i.e. titanium alloy) and coatings (i.e. hydroxyapatite) as the predicate devices
- Sterilization: Similar to the predicates, the proposed iTotal® Hip is intended to be provided sterile (SAL 1.0×10^{-6}) and for single use.

510(K) SUMMARY (PAGE 5 OF 5)

Substantial Equivalence:

The iTotal® Hip Replacement System, subject of this premarket notification is substantially equivalent to the Pipeline Total Hip System (**K112802**, cleared March 09, 2012), the Corail AMT Hip Prosthesis (**K042992**, cleared February 11, 2005), and the Signature Planner and Signature Guides (**K111863**, cleared June 11, 2012). Non-clinical testing was conducted in accordance with applicable FDA guidance documents to confirm that the iTotal® Hip Replacement System is substantially equivalent to the predicate hip systems.

Specifically, the following testing was performed to establish substantial equivalence:

- 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: Adhesive and Abrasive Wear
- Acetabular Bone Screw Testing
- HA Coating Microstructure Characterization
- HA Coating Bonding Strength (Tensile and Static Fatigue) Testing
- HA Coating Shear Fatigue Testing
- Range of Motion Testing
- iJig Drop Testing
- iJig Femoral Neck Resection Simulation
- Characterization of iPoly XE
- Cadaveric Evaluation
- Software Verification/Validation
- Bacterial Endotoxin Testing

All testing has demonstrated that the device is substantially equivalent to the predicate devices.

Conclusion:

Based on the testing conducted, it is concluded that the iTotal® Hip Replacement System is substantially equivalent to the predicate devices: The Pipeline Total Hip System (**K112802,** cleared March 09, 2012), Corail AMT Hip Prosthesis (**K042992**, cleared February 11, 2005), and Signature Planner, Signature Guides (**K111863**, cleared June 15, 2012).