DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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August 24, 2017

Ortho Development Corporation
Drew Weaver
Director of Quality Assurance and Regulatory Affairs
12187 South Business Park Drive
Draper, Utah 84020

Re: K171249
Trade/Device Name: Entrada™ Hip Stem
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, LZO, KWY, KWL
Dated: July 25, 2017
Received: July 27, 2017

Dear Drew Weaver:

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 (DICE) 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 (DICE) 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,

Katherine D. Kavlock -S

for
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)*

K171249

Device Name

Entrada™ hip stem

Indications for Use *(Describe)*

This device is intended for use in total and hemi-hip arthroplasty. The device is intended for uncemented, press-fit use only in cases of:

1. Notably impaired hip joint due to osteoarthritis, rheumatoid arthritis, and/or post traumatic arthritis.
2. Previously failed hip surgery.
3. Proximal femoral neck fractures or dislocation.
4. Idiopathic avascular necrosis of the femoral head.
5. Non-union of proximal femoral neck fractures.
6. Treatment of fractures that are unmanageable using other forms of therapy.
7. Benign or malignant bone tumors, congenital dysplasia or other structural abnormalities where sufficient bone stock exists to properly seat the prosthesis.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

PSC Publishing Services (301) 443-6740 EF

Section 5

510(k) Summary

Name of Sponsor:	Ortho Development® Corporation 12187 South Business Park Drive Draper, Utah 84020
510(k) Contact:	Drew Weaver Director of Quality Assurance and Regulatory Affairs Telephone: (801) 619-3419 Facsimile: (801) 553-9993 DWeaver@orthodevelopment.com
Date Prepared:	August 21, 2017
Proprietary Name:	Entrada™ hip stem
Common Name:	Hydroxyapatite coated hip prosthesis
Classification:	21 CFR 888.3353: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis 21 CFR 888.3390: Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis 21 CFR 888.3360: Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis
Device Product Code:	MEH, LZO, KWY, KWL
Class:	Class II
Primary Predicate Device:	Depuy Synthes Corail Hip Stem (K953111, K093736, K042992, K070554, K123991)
Secondary Predicate Device(s):	Ortho Development® Ovation Tribute (K133386) Exactech Novation Element (K153649)

Description:

Entrada™ hip stem is a single-piece, tapered, collared and non-collared, hydroxyapatite (HA) coated femoral hip stem designed for single use. The stem has a neck with a 12/14 trunnion taper for modular attachment to femoral heads.

Entrada™ hip stem is manufactured from titanium alloy and device fixation is achieved through uncemented press-fit in the medullary canal and through the use of biocompatible HA coating.

The stem has a variety of sizes to accommodate the majority of patients encountered: lengths (95-160mm), horizontal offsets (35-55mm), vertical offsets (29-34mm), resection angle of 45°, and neck angle of 132°. The stem is offered with both standard (STD) and extended (EXT) offsets and with and without a collar.

Indications:

This device is intended for use in total and hemi-hip arthroplasty. The device is intended for uncemented, press-fit use only in cases of:

1. Notably impaired hip joint due to osteoarthritis, rheumatoid arthritis, and/or post-traumatic arthritis.
2. Previously failed hip surgery.
3. Proximal femoral neck fractures or dislocation.
4. Idiopathic avascular necrosis of the femoral head.
5. Non-union of proximal femoral neck fractures.
6. Treatment of fractures that are unmanageable using other forms of therapy.
7. Benign or malignant bone tumors, congenital dysplasia or other structural abnormalities where sufficient bone stock exists to properly seat the prosthesis.

Basis for Substantial Equivalence:

Entrada™ hip stem has the same technological characteristics as the predicate devices. These include:

1. Indications for use
2. Basic design
3. Material
4. Sizes

The following non-clinical mechanical tests were conducted on the worst-case configurations of Entrada™ hip stem:

1. Proximal fatigue
2. Distal fatigue
3. Range of motion analysis

Bacterial endotoxin testing was also performed using LAL pyrogen testing methodology and met the predetermined acceptance criteria.

Therefore the fundamental scientific technology of Entrada™ hip stem is the same as previously cleared devices. The mechanical test results demonstrate that Entrada™ hip stem is safe and effective. No clinical studies were performed.

Conclusions:

Based on similarities in intended use, design, materials, manufacturing methods, packaging, and the mechanical test results, the Entrada™ hip stem is substantially equivalent to the previously cleared predicate devices.