DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 2, 2017

Responsive Orthopedics, LLC
% Ms. Kathy Remsen
Senior Program Manager, Regulatory Affairs
Medtronic, Inc.
2600 Sofamor Danek Drive
Memphis, Tennessee 38132

Re: K163585
Trade/Device Name: Responsive Orthopedics Total Hip Arthroplasty
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: LZO
Dated: April 28, 2017
Received: May 1, 2017

Dear Ms. Kathy Remsen:

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)*

K163585

Device Name
Responsive Orthopedics Total Hip Arthroplasty System

Indications for Use *(Describe)*

The Responsive Orthopedics Total Hip Arthroplasty System is indicated for cementless use only in the following cases:

• Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
• Rheumatoid arthritis;
• Correction of functional deformity;
• Revision procedures where other treatments or devices have failed; and
• Nonunions, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

The Responsive Orthopedics Total Hip Arthroplasty System Acetabular screws are indicated for supplemental fixation of Responsive Orthopedics Acetabular Cup.

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.

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RESPONSIVE ORTHOPEDICS TOTAL HIP ARTHROPLASTY SYSTEM
510(k) SUMMARY
May 2017

I. Submitter

Responsive Orthopedics, LLC
5865 East State Road 14
Columbia City, IN 46725

Phone Number 901-344-1584

Contact Kathy Remsen
Senior Program Manager, Regulatory Affairs

Date Prepared May 24, 2017

II. Device

Name of Device Responsive Orthopedics Total Hip Arthroplasty System

Common Name Semi-constrained total hip prosthesis

Classification Name Prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented -- LZO

Classification Class II

Product Codes LZO
21 CFR 888.3353

Predicates

Depuy Summit Tapered Hip System
K001991, S.E. 08/25/2000

Smith&Nephew -- REFLECTION
K920430, S.E. 07/21/1992
K932755, S.E. 05/06/1994

United Orthopedic Corporation – U2 Acetabular Components
K050262, S.E. 08/15/2005

United Orthopedic Corporation – UTF Stem System
K110245, S.E. 08/04/2011

United Orthopedic Corporation – U2 Femoral Head

K111546, S.E. 07/01/2011
K103479, S.E. 03/10/2011
K022520, S.E. 02/25/2003

Ortho Development Corporation – Ovation™ Hip Stem
K062775, S.E. 01/16/2007

The predicates have not been subject to a design related recall.

III. Product Description

The Responsive Orthopedics Total Hip Arthroplasty (RO THA) System is a total hip system that allows for the restoration of alignment, stability and range of motion, and alleviates pain, by replacing the articulating surfaces of the hip joint. The system includes both femoral and acetabular components. The implants are available in a variety of sizes to accommodate varying patient anatomy.

IV. Indications for Use:

The Responsive Orthopedics Total Hip Arthroplasty System is indicated for cementless use only in the following cases:

- Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed; and
- Nonunions, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

The Responsive Orthopedics Acetabular screws are intended for supplemental fixation of Responsive Orthopedics Acetabular Cup.

V. Comparison of Technological Characteristics

The subject Responsive orthopedics Total Hip Arthroplasty System has the same or similar indications, intended use, and materials as the following FDA-cleared predicates K001991 (S.E. 08/25/2000), K920430 (S.E. 07/21/1992), K932755 (S.E. 05/06/1994), K050262 (S.E. 08/15/2005), K110245 (S.E. 08/04/2011), K111546 (S.E. 07/01/2011), K111546 (S.E. 07/01/2011), K022520 (S.E. 02/25/2003), and K062775 (S.E. 01/16/2007). The predicate and subject devices have the same function.

VI. Materials

The RO THA Femoral Stems and acetabular cups are manufactured from forged Ti-6Al-4V ELI conforming to ASTM F136 and ASTM F620.
The RO THA Acetabular Screws are manufactured from machined Ti-6AL-4V ELI conforming to ASTM F136.
The RO THA Femoral heads are manufactured from Co-Cr-Mo alloy conforming to ASTM F1537 and from BIOLOX® delta.
The RO THA Acetabular Liners are manufactured from conventional, non-crosslinked GUR1020 UHMWPE conforming to ASTM F648.

VII. Performance Data

The following performance bench testing was performed for the Responsive Orthopedics Total Hip Arthroplasty System in support of the substantial equivalence determination.

The tests completed were:

- Femoral Stem Fatigue Testing
- Femoral Neck Fatigue Testing
- Axial Disassembly Testing
- Fretting and Corrosion Testing
- Cup and Liner Disassembly Testing
- Screw Characteristics Testing
- Ceramic Femoral Head Comparative Burst Testing
- Ceramic Femoral Head Fatigue and Post-Fatigue Burst Testing
- Ceramic Femoral Head Axial Disassembly Testing
- Ceramic Femoral Head Torque Testing
- Pyrogenicity Testing

Wear and impingement performance of the conventional, non-crosslinked polyethylene liners in the subject system were addressed based on a comparison of the minimum thickness in the rim and load-bearing regions of the liners with the predicate devices.

All tests which are in relation to the porous structure characterization (physical, chemical or mechanical) are in Master File MAF – 628 (owned by APS Materials) and are not included in this 510(k).

The subject devices met the pre-determined acceptance criteria for all tests. Therefore, design verification testing determined that the subject devices are substantially equivalent to the predicate devices.

VIII. Conclusions

Based on the test results and additional supporting information provided in this pre-market notification, the subject devices demonstrated substantial equivalence to the legally marketed predicate devices.