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 12, 2015

Responsive Orthopedics LLC
% Jude Paganelli
Cor Medical Ventures LLC
101 North Acacia Avenue, Suite 106
Solana Beach, California 92075

Re: K150496
Trade/Device Name: Responsive Orthopedics Total Knee Arthroplasty System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: March 13, 2015
Received: March 16, 2015

Dear Jude Paganelli:

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" (21CFR 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 yours,

Lori A. Wiggins -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)*
K150496

Device Name
Responsive Orthopedics Total Knee Arthroplasty System

Indications for Use *(Describe)*
The Responsive Orthopedics Total Knee Arthroplasty System is indicated for use in knee arthroplasty in skeletally mature patients with the following conditions:

- noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
- inflammatory degenerative joint disease including rheumatoid arthritis;
- correction of functional deformity;
- revision procedures where other treatments or devices have failed; and treatment of fractures that are unmanageable using other techniques.

The Responsive Orthopedics Total Knee Arthroplasty System is for cemented use only.

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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SECTION 5

510(K) SUMMARY

SUBMITTER:

Submitted By:

Company Name: Responsive Orthopedics LLC
Address: 1755 Concordia Street
Wayzata, MN 55391
Telephone: 858-774-7891

CONTACT PERSON: Jude Paganelli

DATE PREPARED: February 23, 2015

TRADE NAME: Responsive Orthopedics Total Knee Arthroplasty System

COMMON NAME: RO Knee System

CLASSIFICATION NAME: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis. (21 CFR 888.3560)

PRODUCT CODE: JWH

SUBSTANTIAL EQUIVALENCE:
The Responsive Orthopedics Total Knee Arthroplasty System is substantially equivalent to the predicate devices in all facets including: function, design, performance, material, and intended use. The predicate devices for the Responsive Orthopedics Total Knee Arthroplasty System are:

DePuy Sigma® Knee System (K943462, K961685, K032151, K950010)
Wright Medical Technology EVOLUTION™ Medial Pivot (K093552)
Consensus Knee System (K932837)

DEVICE DESCRIPTION:
The Responsive Orthopedics Total Knee Arthroplasty System is a total knee system for the restoration of alignment, stability and range of motion, and alleviation of pain, by replacing the articulating surfaces of the knee joint. The system includes femoral, tibial and patellar components available in cruciate retaining, ultra-conforming cruciate sacrificing, medial-pivot cruciate sacrificing and posterior stabilizing versions.

MATERIALS:
The RO TKA femoral components and tibial trays are manufactured from cast Co-Cr-Mo alloy conforming to ASTM F75.
The RO TKA poly inserts and patella components are manufactured from non-crosslinked GUR 1050 Ram Extruded UHMWPE conforming to ASTM F648.

INDICATIONS FOR USE:
The Responsive Orthopedics Total Knee Arthroplasty System is indicated for use in knee arthroplasty in skeletally mature patients with the following conditions:

- noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
- inflammatory degenerative joint disease including rheumatoid arthritis;
- correction of functional deformity;
- revision procedures where other treatments or devices have failed; and treatment of fractures that are unmanageable using other techniques.

The Responsive Orthopedics Total Knee Arthroplasty System is for cemented use only.

PERFORMANCE TESTING:
The following bench testing was performed on the Responsive Orthopedics Total Knee Arthroplasty System**:**

Tibial Baseplate Fatigue Testing per ASTM F1800
UHMWPE Tibial Bearing Components (minimum thickness justification)
Posterior-Stabilized Tibial Bearing Component Shear Fatigue Testing
Range of Motion and Constraint Testing per ASTM F1223
Tibiofemoral Contact Area/Stress per ASTM F2083
Component Interlock Strength per ASTM F1814

CONCLUSIONS:
The Responsive Orthopedics Total Knee Arthroplasty System has shown to be substantially equivalent to legally marketed predicates based on indications for use, technological characteristics, performance testing and comparison to predicate devices.