Medtronic Advanced Energy
Gina Cunsolo
Regulatory Affairs Specialist
180 International Drive
Portsmouth, New Hampshire 03801

July 26, 2019

Re: K183129
Trade/Device Name: Medtronic Total Hip Arthroplasty 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
Dated: June 25, 2019
Received: June 26, 2019

Dear Gina Cunsolo:

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

Indications for Use

The following is the Indications for Use Statement. Refer to Attachment 1 for FDA Form 3881.

Device Name:
Medtronic Total Hip Arthroplasty System

Indications:

The Medtronic Total Hip Arthroplasty System is indicated for cement-less 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 Medtronic Total Hip Arthroplasty System Acetabular Screws are intended for supplemental fixation of the associated Medtronic Acetabular Cup.

510(k) Summary

Submitter: Medtronic Advanced Energy
180 International Drive
Portsmouth, NH 03801

Contact Person: Gina Cunsolo
Regulatory Affairs Specialist
Phone: (603) 842-6210
Fax: (603) 742-1488
E-mail: Gina.M.Cunsolo@medtronic.com

Date Summary Prepared: November 9, 2018

Device Trade Name: Medtronic Total Hip Arthroplasty System

Common Name: Hip Prosthesis

Classification Name: 21 CFR 888.3358 – Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis

21 CFR 888.3353 – Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis

Product Code: LPH, LZO

Predicate Devices: Responsive Orthopedics Total Hip Arthroplasty System (K163585)

Device Description: The Medtronic Total Hip Arthroplasty System is a total hip system for the restoration of alignment, stability range of motion, and alleviation of pain, by replacing the articulating surfaces of the hip joint. The system includes femoral and acetabular components. The implants are available in a variety of sizes to accommodate varying patient anatomy.

New acetabular components including highly crosslinked UHMWPE acetabular liners and porous coated cups are the subject of this 510(k).

Traditional 510(k) Medtronic Total Hip Arthroplasty System

Indications for Use:

The Medtronic 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 Medtronic Total Hip Arthroplasty System Acetabular Screws are intended for supplemental fixation of the associated Medtronic Acetabular Cup.

Technological Characteristics:

The Medtronic Total Hip Arthroplasty System is similar to that of the predicate devices, as it still has the same indications for use and intended use of the predicate. The difference between the two is the material change of the acetabular liner from a conventional polyethylene to a highly crosslinked UHMWPE liner.

Summary of Non-Clinical Testing:

The following tests were completed to support the addition of a highly crosslinked UHMWPE acetabular liner and cup:

- Wear Testing per:
  - ISO 14242-1:2014 Implants for Surgery – Wear of total hip-joint prostheses – Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test
  - ISO 14242-2: 2016 Implants For Surgery - Wear Of Total Hip-Joint Prostheses - Part 2: Methods Of Measurement
  - ASTM F2003-02: 2015 Standard Practice For Accelerated Aging Of Ultra-High Molecular Weight Polyethylene After Gamma Irradiation In Air
- Impingement Testing per:
  - ASTM F2582-14: Standard Test Method For Impingement Of Acetabular Prostheses
  - ASTM F2003-02: 2015 Standard Practice For Accelerated Aging Of Ultra-High Molecular Weight Polyethylene After Gamma Irradiation In Air
- Cup and Liner Disassembly Testing per
  - ASTM F1820-13 Standard Test Method For Determining The Forces For Disassembly Of Modular Acetabular Devices
- Biocompatibility per
  - ISO 10993-12: 2012, Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials

- ISO 10993-17 Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances
- ISO 10993-18, 2005, Biological Evaluation of Medical Devices – Part 18: Chemical Characterization of Materials

- Material Characterization per:
  - ASTM F2565 Standard Guide For Extensively Irradiation-Crosslinked Ultra-High Molecular Weight Polyethylene Fabricated Forms For Surgical Implant Applications

Summary of Clinical Tests: Clinical Testing was not required for these products.

Conclusion: Based on the indications for use, performance characteristics, and bench testing completed on the Medtronic Total Hip Arthroplasty System, the subject device is equivalent to the predicate device.