



Food and Drug Administration
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Silver Spring, MD 20993-0002

Zimmer, Inc.
Ms. Rhonda Myer
Project Manager, Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581

October 26, 2016

Re: K161830

Trade/Device Name: Zimmer M/L Taper Hip Prosthesis
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, MEH
Dated: September 23, 2016
Received: September 26, 2016

Dear Ms. Myer:

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 Parts 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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

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Device Name

M/L Taper Hip Prosthesis

Indications for Use (Describe)

Total hip replacement for the following: severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, nonunion of previous fractures of the femur; congenital hip dysplasia, protrusio acetabuli, slipped capital femoral epiphysis; disability due to previous fusion; previously failed endoprostheses, and/or total hip components in the affected extremity and acute femoral neck fractures.

Hemi-hip replacement for the following: fracture dislocation of the hip; elderly, debilitated patients when a total hip replacement is contraindicated; irreducible fractures in which adequate fixation cannot be obtained; certain high subcapital fractures and comminuted femoral neck fractures in the aged; nonunion of femoral neck fractures; secondary avascular necrosis of the femoral head; pathological fractures of the femoral neck; and osteoarthritis in which the femoral head is primarily affected.

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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510(k) Summary

Sponsor: Zimmer, Inc.
P.O. Box 708
Warsaw, IN 46581-0708

Contact Person: Rhonda Myer
Project Manager, Regulatory Affairs
Telephone: (574) 371-9659
Fax: (574) 372-4710

Date: June 30, 2016

Trade Name: M/L Taper Hip Prosthesis

Product Code / Device: **LZO** - Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous, Uncemented
MEH - Prosthesis, Hip, Semi-Constrained, Uncemented, Metal/Polymer, Non-Porous, Calicum-Phosphate

Regulation Number / Description: 21 CFR § 888.3353 - Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.

Predicate Device: M/L Taper Hip Prosthesis, K032726 (cleared October 22, 2003) and K042337 (cleared November 4, 2004)

Device Description: The Zimmer M/L Taper Hip Prosthesis is a modular, titanium alloy femoral stem designed to replace the proximal femur in total hip arthroplasty. It is flat, collarless and features a proximal-to-distal taper in the mediolateral (M/L) plane. The wedge-shaped prosthesis is designed for cementless use

and is circumferentially porous-coated with titanium alloy plasma spray over the proximal body region. A subset of the subject devices are coated with Calcicoat hydroxyapatite tricalcium phosphate coating (HA/TCP) over the porous coating.

Intended Use:

Total hip replacement for the following: severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, nonunion of previous fractures of the femur; congenital hip dysplasia, protrusion acetabuli, slipped capital femoral epiphysis; disability due to previous fusion; previously failed endoprostheses, and/or total hip components in the affected extremity and acute femoral neck fractures.

Hemi-hip replacement for the following: fracture dislocation of the hip; elderly, debilitated patients when a total hip replacement is contraindicated; irreducible fractures in which adequate fixation cannot be obtained; certain high subcapital fractures and comminuted femoral neck fractures in the aged; nonunion of femoral neck fractures; secondary avascular necrosis of the femoral head; pathological fractures of the femoral neck; and osteoarthritis in which the femoral head is primarily affected.

Comparison to Predicate Device:

The subject M/L Taper Hip Prosthesis is identical to the predicate devices in design, material, geometry, plasma spray and HA/TCP coatings. The subject device is packaged and sterilized using the same materials and processes as the predicate devices. The subject device also has the same intended use, indications for use, and fixation methods as the predicate devices. The only differences between the subject and predicate devices are the changes in the manufacturing process, which include using a forged blank instead of a wrought blank, using mass disc finishing in addition to hand polishing, and a change to the laser etch type and location.

Performance Data (Nonclinical and/or Clinical):

Non-clinical performance testing demonstrated that the M/L Taper Hip Prosthesis meets performance requirements. Performance testing performed included proximal fatigue testing to ISO 7206-6 and distal fatigue testing to ISO 7206-4. Bacterial endotoxin testing was conducted and met the endotoxin limits as described in USP39-NF34 Chapter 161.

Clinical data and conclusions were not needed for this device.