



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

Total Joint Othopedics, Inc.
Chris Weaber
Product Development, Regulatory Manager
1567 E. Stratford Avenue
Salt Lake City, Utah 84106

July 24, 2017

Re: K171962

Trade/Device Name: Klassic HD[®] Hip 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, MBL, LZO

Dated: June 29, 2017

Received: June 30, 2017

Dear Chris Weaber:

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

Indications for Use

510(k) Number (if known)

K171962

Device Name

Klassic HD® Hip System

Indications for Use (Describe)

The Klassic HD® Hip System is intended for prosthetic replacement without bone cement in treatment of the following:

- Patient conditions of non-inflammatory degenerative joint disease (NIDJD): avascular necrosis, osteoarthritis, ankylosis, protrusio acetabuli and painful hip dysplasia.
- Patient conditions of inflammatory joint disease (IJD): rheumatoid arthritis.
- Those patients with failed previous surgery where pain, deformity, or dysfunction persists.
- Revision of a previously failed hip arthroplasty.
- Patients who require a total hip replacement.

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

Manufacturer: Total Joint Orthopedics, Inc.
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Salt Lake City, UT 84106
Phone: 801.486.6070
Fax: 801.486.6117

Contact: Mr. Chris Weaber
Product Development, Regulatory Manager

Prepared By: Musculoskeletal Clinical Regulatory Advisers, LLC
1050 K Street, NW, Suite 1000
Washington, DC 20001
Phone: 202.552.5800
Fax: 202.552.5798

Date Prepared: June 29, 2017

Device Trade Name: Klassik HD[®] Hip System

Common Name: Femoral Hip Stem

Classifications: 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

Class II

Product Codes: LPH, LZO, MBL

Indications for Use:
The Klassik HD[®] Hip System is intended for prosthetic replacement without bone cement in treatment of the following:

- Patient conditions of non-inflammatory degenerative joint disease (NIDJD): avascular necrosis, osteoarthritis, ankylosis, protrusio acetabuli and painful hip dysplasia.
- Patient conditions of inflammatory joint disease (IJD): rheumatoid arthritis.
- Those patients with failed previous surgery where pain, deformity, or dysfunction persists.
- Revision of a previously failed hip arthroplasty.
- Patients who require a total hip replacement.

Device Description:

The Klassik HD[®] Hip System employs prostheses designed to help surgeons restore hip joint biomechanics intra-operatively. The purpose of this Special 510(k) is to add larger sizes of the Klassik[®] Blade Femoral Stems and add a new material for previously cleared Klassik[®] Blade Femoral Stems and Klassik[®] Blade Offset Femoral Stems.

Predicate Devices:

The modified Klassik HD[®] Hip System is substantially equivalent to the predicate Klassik HD[®] Hip System (K100445, K151440) with respect to indications, design, materials and function. The information summarized in the Design Control Activities Summary demonstrates that the modified Klassik[®] Blade Femoral Stems and modified Klassik[®] Blade Offset Femoral Stems met the pre-determined acceptance criteria for the verification activities.

Substantial Equivalence:

The company performed worst case fatigue testing of the Klassik[®] Blade Femoral Stems and Klassik[®] Blade Offset Femoral Stems, as well as porous coating characterization. The fatigue and characterization results demonstrated that the modified stems are substantially equivalent to the predicate components. Additionally, the Klassik HD[®] Hip System is in compliance with LAL testing requirements for orthopedic implants.