



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

Total Joint Orthopedics, Incorporated
Mr. Chris Weaber
Manufacturing Development Engineer
1567 East Stratford Avenue
Salt Lake City, Utah 84106

September 3, 2015

Re: K151440

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

Dated: August 6, 2015

Received: August 7, 2015

Dear Mr. 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" (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,

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)
Unknown K151440

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

1. 510(k) Summary

- Manufacturer:** Total Joint Orthopedics, Inc.
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- Contact:** Mr. Chris Weaber
Manufacturing Development Engineer
- Prepared By:** Musculoskeletal Clinical Regulatory Advisers, LLC
1331 H Street, NW, 12th Floor
Washington, DC 20005
Phone: 202.552-5800
Fax: 202.552.5798
- Date Prepared:** May 28, 2015
- Device Trade Name:** Klassic 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 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.

Device Description:

The Klassic HD[®] Hip System employs a prosthesis designed to help surgeons restore hip joint biomechanics intraoperatively by independently addressing the size of the femur and acetabulum, leg length, offset and version. The purpose of this 510(k) is to add Klassic[®] Blade Femoral Stems and Klassic[®] Blade Offset Femoral Stems to the Klassic HD[®] Hip System. The modified stems can be mated with the previously cleared metal (CoCrMo) or ceramic femoral heads and UHMWPE acetabular components of the Klassic HD[®] Hip System.

Predicate Devices:

The modified Klassic HD[®] Hip System is substantially equivalent to the predicate Klassic HD[®] Hip System (K100445), Klassic HD[®] Offset Femoral Stem (K133832), and Klassic HD[®] Extended Offset Femoral Head (K131454) with respect to indications, design, and function.

Substantial Equivalence:

The company performed Range of Motion and worst case fatigue testing of the Klassic[®] Blade Femoral Stems and Klassic[®] Blade Offset Femoral Stems. Engineering analyses were conducted to evaluate disassembly properties and porous coating properties of the Klassic[®] Blade Femoral Stems and Klassic[®] Blade Offset Femoral Stems. The test results and analyses demonstrated that the modified stems are substantially equivalent to the predicate components.