

**510(k) SUMMARY**

---

**510(k) Notification K100445**

**GENERAL INFORMATION**

**Applicant:**

Total Joint Orthopedics, Inc.  
1567 E Stratford Ave  
Salt Lake City, UT 84106  
Phone: 801-486-6070  
Fax: 801-486-6117

DEC - 3 2010

**Contact Person:**

Kit Cariquitan  
Vice President, Regulatory Affairs  
Experien Group, LLC  
155-A Moffett Park Drive Suite 210  
Sunnyvale, CA 94089  
Phone: 408-400-0856  
Fax: 408-400-0865

**Date Prepared:** October 22, 2010

**DEVICE INFORMATION**

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.

**Classification:**

21 CFR§888.3358, Class II

**Product Code:**

LPH, MBL, LWJ

**Trade Name:**

Klassic HD™ Hip System

**Generic/Common Name:**

Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis

**510(k) SUMMARY (CONT.)**

---

**PREDICATE DEVICES**

- Accelerated Innovation, L.L.C., Accin™ Hip System (K073068)
- Centerpulse Orthopedics Ltd., Alloclassic™ Zweymueller™ SL/SLL Femoral Stem (K030373)
- Encore Orthopedics, Inc., Foundation® Porous Hip Stem (K991226)
- Howmedica Osteonics Corp., V-40™/C-Taper Adapter Sleeve (K051737)
- Encore Medical, L.P., BioloX® *delta* Ceramic Femoral Head and BioloX® *delta* Ceramic Femoral Offset Sleeve (K082844)
- Encore Medical, L.P., Foundation® Porous Coated (FMP™) Acetabular Shells (K072888)
- Smith & Nephew, Inc., R3 Multi-Hole Shells and 36mm XLPE Acetabular Liners (K092386)
- Apex Surgical, LLC, Apex Modular™ Acetabular Cup (K031110)
- OMNI Life Science, Inc., Apex HCLA™ Acetabular Cup Liners (K062489)
- OMNI Life Science, Inc., ApeX-LNK Poly™ Acetabular Cup Liners (K073150)

**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.

**PRODUCT DESCRIPTION**

The Klassic HD Hip System is simple, easy to use, and based on clinically proven design philosophies. 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 Klassic HD Hip System is comprised of modular components with varying sizes available for each component for a cementless hip joint replacement application. Components of the Klassic HD Hip System include the femoral stem, femoral head, femoral head adapter sleeve, acetabular cup, acetabular insert and cancellous bone screws. The implantable components are intended for single-use for a single patient only.

The titanium alloy femoral stems feature a neck shaft angle of 131°. Femoral stems are available in sizes 1-9 with neck lengths of 26-38mm in 4mm increments and stem lengths

**510(k) SUMMARY (CONT.)**

---

of 110-150mm in 5mm increments. The stem's proximal surface is either grit-blasted or porous-coated. Cobalt chromium femoral heads available in 32mm or 36mm diameters attach either directly to the stem trunnion or through the use of an adapter sleeve thereby offering -3.5mm, neutral, +3.5mm and +7mm offsets. The titanium alloy, hemispherical acetabular cups are available in 9 sizes ranging from 48-64mm in 2mm increments and incorporate a porous coated outer surface. The UHMWPE acetabular inserts attach through a snap-fit mechanism to the acetabular cup. Conventional, noncross-linked (32mm inner diameter) and cross-linked (32mm and 36mm inner diameter) UHMWPE insert versions are available in the Klassic HD Hip System. Both types of UHMWPE material have been utilized in previously cleared devices. Optional 6.5mm cancellous, titanium alloy bone screws allow for additional fixation of the acetabular cup to the bone.

**TECHNOLOGICAL CHARACTERISTICS**

The technological characteristics of the Klassic HD Hip System are similar to the predicate devices. Performance data were provided to support the determination of substantial equivalence.

**SUBSTANTIAL EQUIVALENCE**

The indications for use for the Klassic HD Hip System are substantially equivalent to the indications for use for the predicate devices. Any differences in the technological characteristics between the devices do not raise any new issues of safety or effectiveness. Thus, the Klassic HD Hip System is substantially equivalent to the predicate devices.

**TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION**

Extensive bench testing was conducted on the Klassic HD Hip System to evaluate the performance of the device and to support a determination of substantial equivalence to the predicate devices. Performance testing conducted for the worst case femoral constructs addressed proximal fatigue, distal fatigue, axial disassembly and torsional disassembly. Performance testing conducted for the worst case acetabular constructs included push-out, lever-out and torque to rotation testing as well as an evaluation of wear characteristics of the insert materials. The static breaking strength and the pull-out strength of the worst case cancellous bone screw were also assessed. The porous coating was characterized per FDA's "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Opposing Bone or Bone Cement" dated April 28, 1994.

All testing was performed in accordance with recognized standards. Results confirm that all components of the Klassic HD Hip System exhibit the appropriate mechanical characteristics for total hip joint replacement, and are substantially equivalent to the predicate devices.

**SUMMARY**

The Klassic HD Hip System is substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

Total Joint Orthopedics, Inc.  
% Mr. Kit Cariquitan  
Vice President, Regulatory Affairs  
Regulatory Consultant for Total Joint Orthopedics, Inc.  
Experien Group, LLC  
155-A Moffett Park Drive Suite 210  
Sunnyvale, California 94089

DEC - 3 2010

Re: K100445

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, LWJ  
Dated: October 22, 2010  
Received: October 25, 2010

Dear Mr. Cariquitan:

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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  
Director  
Division of Surgical, Orthopedic,  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

---

510(k) Number (if known): K100445

Device Name: Klassic HD™ Hip System

DEC: - 3. 2010

**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.

Prescription Use X  
(21 CFR Part 801 Subpart D)

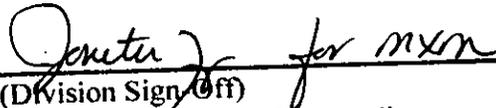
and/Or

Over the Counter Use \_\_\_\_\_  
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K100445