

JUL 03 2013

## 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this information serves as a Summary of Safety and Effectiveness for the use of the DYNASTY® Acetabular System with Ceramic.

**Submitted By:** Wright Medical Technology, Inc.  
5677 Airline Rd, Arlington TN, 38002  
(800) 238-7188

**Date:** March 14, 2013

**Contact Person:** Yuan Li, Ph.D.  
*Regulatory Affairs Specialist II*

**Proprietary Name:** DYNASTY® Acetabular System with Ceramic

**Common Name:** Femoral Head

**Classification Name and Reference:** 888.3353 prosthesis, hip, semi-constrained,  
metal/ceramic/polymer, cemented or non-porous,  
uncemented Class II

**Subject Product Code and Panel Code:** Orthopedics/87/LZO

**Predicate Devices:** DYNASTY® Acetabular System  
510(k)s: K072656

### DEVICE INFORMATION

#### **A. Intended Use**

Wright Medical total hip systems are indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed

#### **B. Device Description**

The DYNASTY® Acetabular System with Ceramic is manufactured from alumina matrix composite. The components are offered in sizes ranging from 32mm to 40mm.

#### **C. Substantial Equivalence Information**

The subject DYNASTY® Acetabular System with Ceramic is indicated to be paired with the following acetabular components, and 510(k) information is summarized in Table 1 and 2.

**Table 1. Compatible Shells, Including 510(k) Information**

510(k)	Device Name
K122382	DYNASTY® 10 Hole Revision Shells
K122382	DYNASTY® BIOFOAM® 3-Hole Shells
K122382	DYNASTY® BIOFOAM® Solid Shells
K122382	DYNASTY® BIOFOAM® 5 Hole Shells
K082924	DYNASTY® BIOFOAM® Shells
K061547; cleared for alumina-polyethylene under K072656	DYNASTY® Porous 3-Hole Shells, 50 to 58mm
K070785; cleared for alumina-polyethylene under K072656	DYNASTY® Porous 3-Hole Shells, 60 to 68mm

**Table 2. Compatible Liners, Including 510(k) Information**

510(k)	Device Name
K061547; cleared for alumina-polyethylene under K072656	DYNASTY® Standard A-CLASS® Poly Liners
K070785; cleared for alumina-polyethylene under K072656	DYNASTY® 15° A-CLASS® Poly Liners
K070785; cleared for alumina-polyethylene under K072656	DYNASTY® Standard A-CLASS® Revision Liners (Group E, F, G, H)
K070785; cleared for alumina-polyethylene under K072656	DYNASTY® 15° A-CLASS® Revision Liners (Group E, F, G, H)
K082924	DYNASTY® Standard A-CLASS® Revision Liners (Group J, K)
K082924	DYNASTY® 15° A-CLASS® Revision Liners (Group J, K)

The subject DYNASTY® Acetabular System with Ceramic is indicated to be paired with the following femoral components, and 510(k) information is summarized in Table 3.

**Table 3. Compatible Femoral Components, Including 510(k) Information**

510(k)	Device Name
K003016	PRO-FEMUR R
K012091	PRO-FEMUR
K021346	STEM HIP REPLACEMENT SYSTEM
K041114	PROFEMUR TAPERED HIP STEM
K041586	PROFEMUR S HIP STEM
K051995	PROFEMUR RENAISSANCE HIP STEM
K052915	PROFEMUR XTR HIP STEM
K053588	PROFEMUR LX HIP STEM
K060358	PROFEMUR TL HIP STEM
K080663	PROFEMUR LX REVISION 5/8 COATED HIP STEM
K081090	PROFEMUR LX 5/8 COATED HIP STEM
K091423 K100866	PROFEMUR HIP SYSTEM MODULAR NECKS
K110399	GLADIATOR PLASMA CLASSIC HIP STEM
K111698	PROFEMUR(R) E CEMENTLESS HIP STEM
K111699	PROFEMUR(R) Z TITANIUM PLASMA SPRAYED HIP STEM
K111910	GLADIATOR HIP STEM
K112080	PRESERVE HIP STEM

K112150	PROFEMUR GLADIATOR HA HIP STEM
K121221	PROFEMUR Z REVISION HIP STEM
K123434	PROFEMUR Z CLASSIC STEM
K123688	PROFEMUR TL CLASSIC STEM

The design features of the subject devices are substantially equivalent to those of the predicate DYNASTY® Acetabular system devices cleared under K072656. The indications of the subject device are identical to the predicate. Specific warnings are added in the package insert. The fundamental scientific technology of the modified devices has not changed relative to the predicate devices. The safety and effectiveness of the DYNASTY® Acetabular System with Ceramic is adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

#### D. Nonclinical Testing

The subject DYNASTY® Acetabular System with Ceramic was evaluated mechanically, tribologically, and chemically. Wear of the subject bearing was evaluated for comparison to a metal-poly bearing cleared under K052026. The mechanical testing on the subject and predicate devices was performed on wrought Cobalt Chrome modular neck spigots cleared under K091423 and K100866. The testing shows that it can be concluded that the subject ceramic material can be expected to perform well under normal physiological chemical and mechanical conditions.

#### E. Clinical Testing

Clinical data was not provided for the subject devices.

#### F. Conclusion

The design features of the subject devices are substantially equivalent to the predicate devices. The instrument list and materials remain identical to those cleared under K122382. The safety and effectiveness of the DYNASTY® Acetabular System with Ceramic is adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.



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

July 3, 2013

Wright Medical Technology, Incorporated  
% Mr. Dean Nachtrab  
Regulatory Affairs Specialist  
5677 Airline Road  
Arlington, Tennessee 38002

Re: K130376

Trade/Device Name: DYNASTY® Acetabular System with Ceramic

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

Dated: May 29, 2013

Received: June 3, 2013

Dear Mr. Nachtrab:

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

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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 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>. 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,

**Erin Keith**

For

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

Enclosure

DYNASTY® Acetabular System with Ceramic  
Traditional 510(k)  
Tab: Indications for Use Statement

### INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K130376

Device Name: DYNASTY® Acetabular System with Ceramic

Indications for Use:

Wright Medical total hip systems are indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed

Prescription Use  X   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

**Elizabeth L. Frank -S**

Division of Orthopedic Devices