K082924 (pg 1/2)

510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

MAR - 6 2009

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.

Submitted By:	Wright Medical Technology, Inc.
Date:	September 30, 2008
Contact Person:	Matt Paul Regulatory Affairs Specialist II
Proprietary Name:	DYNASTY® Acetabular System
Common Name:	Acetabular Shell Acetabular Liner Femoral Head
Classification Name and Reference:	21 CFR 888.3330 Prosthesis, hip, semi-constrained (metal uncemented acetabular component) - Class III
Device Product Code and Panel Code:	Orthopedics/87/KWA, JDL

DEVICE INFORMATION

A. Intended Use

The DYNASTY® Acetabular System is 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.

The size 50 and 54mm ceramic femoral heads are only intended for patients with giganticism or malunion of the acetabulum, and/or revision.

The DYNASTY® Acetabular Shell is for both cemented and uncemented use and is a single use device.

B. Device Description

The design features of the DYNASTY® Acetabular System are summarized below:

- Shells manufactured from Titanium alloy, coated with CP Titanium
- Shell sizes: 46mm-76mm outer diameter
- Liners manufactured from UHMW Polyethylene
- Polyethylene liner sizes: 28mm, 50mm, 54mm inner diameter
- Liners manufactured from Cobalt Chrome alloy
- Cobalt Chrome liner sizes: 52mm, 56mm inner diameter
- Heads manufactured from Alumina Ceramic
- Head sizes: 50mm, 54mm diameter

C. Substantial Equivalence Information

The indications for use of the DYNASTY® Acetabular System are identical to the previously cleared predicate devices. The design features and materials of the subject devices are substantially equivalent to those of the predicate devices. The fundamental scientific technology of the modified device has not changed relative to the predicate devices. The safety and effectiveness of the DYNASTY® Acetabular System are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Wright Medical Technology, Inc.
% Mr. Matt Paul
Sr. Regulatory Affairs Specialist
5677 Airline Road
Arlington, Tennessee 38002

MAR - 6 2009

Re: K082924
Trade/Device Name: DYNASTY® Acetabular System
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
Regulatory Class: Class III
Product Code: KWA, JDL
Dated: February 4, 2009
Received: February 5, 2009

Dear Mr. Paul:

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.

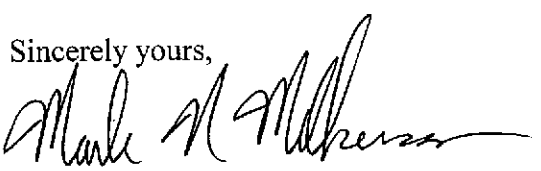
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082924 (pg 1/1)

Device Name: DYNASTY® Acetabular System

Indications For Use:

The DYNASTY® Acetabular System is 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:

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Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark A Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082924