K062775

JAN 16 2007

Ortho Development Corporation
12187 S. Business Park Drive • Draper, Utah 84020
Phone (801) 553-9991 • Fax (801) 553-9993
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510(k) Summary

Date: January 8th, 2007

Applicant: Ortho Development Corporation

Contact Person: Ms. Johanne Young
Quality Systems Engineer
Ortho Development Corp.
12187 Business Park Drive
Draper, Utah 84020
PH: 801-619-3450
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EM: jyoung@orthodevelopment.com

Proprietary Name: Ovation™ Hip Stem

Common Name: Hip Prosthesis, Uncemented Femoral Stem

Classification Names:
1. Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis. (211 CFR 888.3358) (In accordance with 21 CFR 807.87(a)).

2. Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis. (21 CFR 888.3353).

Legally Marketed Device To Which Substantial Equivalence Is Claimed:
K043537 - Taperloc® 12/14 Femoral Components (Biomet)
K991485 - Synergy™ Porous Hip Stem (Smith & Nephew)
K921181, K020580, K043537, K921301 - Mallory-Head® Total Hip System and Bi-Metric® Hip Femoral Components and Taperloc Femoral Stems (Biomet)
K972228, K020572 - Meridian® Titanium Femoral Stems and Accolade TMZF® Femoral Stems (Howmedica)
K964218 - Perfecta® Plasma Spray Hip Stems (Wright Medical)

Device Description: The Ovation™ Hip Stem is a one-piece, tapered prosthesis, designed for single, uncemented use. Device fixation is achieved by an optimal press-fit in the medullary canal. The stem will be available in a variety of sizes to accommodate the majority of patients

encountered with lengths of 110-165mm, horizontal offsets of 33-47mm, vertical offsets of 27-36mm, and neck angles of 127° and 132°. The stem is manufactured from Titanium Alloy (ASTM F-136, Ti-6Al-4V ELI) and the proximal portion of the stem is plasma sprayed with titanium alloy (ASTM F-1580). The finished stem is passivated per ASTM F-86.

Intended Use: The Ovation™ Hip Stem is used in uncemented total hip replacement in cases of:

1. Notably impaired hip joint due to osteoarthritis, rheumatoid arthritis and/or post traumatic arthritis.
2. Previously failed surgery.
3. Proximal femoral neck fractures or dislocation.
4. Idiopathic avascular necrosis of the femoral head.
5. Non-union of proximal femoral neck fractures.
6. Treatment of fractures that are unmanageable using other forms of therapy.
7. Benign or malignant bone tumors, congenital dysplasia or other structural abnormalities where sufficient bone stock exists to properly seat the prosthesis.

Summary Of Technologies: The overall design, materials and processing methods of the Ovation™ Hip Stem are similar to the predicate devices.

Non-Clinical Testing: Engineering analysis and mechanical testing has demonstrated equivalence between the Ovation™ Hip Stem and the predicate devices.

Clinical Testing: None provided

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ortho Development Corporation
% Ms. Johanne Young
12187 South Business Park Drive
Draper, Utah 84020

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Re: K062775
Trade/Device Name: Ovation™ Hip Stem
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, LZO
Dated: December 20, 2006
Received: December 22, 2006

Dear Ms. Young:

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.

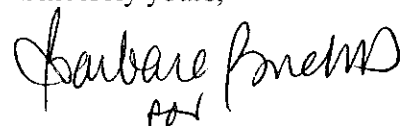
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (240) 276-0210 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its 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): K062775

Device Name: Ovation™ Hip Stem

Indications For Use:

The Ovation™ Hip Stem is used in non-cemented total hip replacement in cases of:

1. Notably impaired hip joint due to osteoarthritis, rheumatoid arthritis and/or post traumatic arthritis.
2. Previously failed surgery.
3. Proximal femoral neck fractures or dislocation.
4. Idiopathic avascular necrosis of the femoral head.
5. Non-union of proximal femoral neck fractures.
6. Treatment of fractures that are unmanageable using other forms of therapy.
7. Benign or malignant bone tumors, congenital dysplasia or other structural abnormalities where sufficient bone stock exists to properly seat the prosthesis.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Richard

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

510(k) Number K062775