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510(k) Summary of Safety and Effectiveness

Line Extension to the Biolox® Delta Ceramic Femoral Heads

Proprietary Name:	Biolox® Delta Ceramic Femoral Heads
Common Name:	Artificial femoral head component
Proposed Regulatory Class:	Class II
Classification:	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis, 21 CFR §888.3353.
Device Product Code:	87 LZO: Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous, Uncemented.
For Information contact:	Karen Ariemma, Senior Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Telephone: (201) 831-5718 Fax: (201) 831-6038 Email: karen.ariemma@stryker.com
Date Summary Prepared:	June 13, 2005

Device Description

The subject Biolox® Delta Ceramic Femoral Heads mate with Howmedica Osteonics' C-Taper femoral stems fabricated from Titanium or CoCr alloys. The Biolox® Delta Ceramic Femoral Heads are available in 28, 32 and 36 mm diameters and a variety of neck offsets.

Device Modification

This submission adds additional femoral heads (36 mm diameter –5.0 mm offset heads and 36 mm diameter +7.5 mm offset heads) and allows for use of the Biolox® Delta Ceramic Femoral Heads with the Trident® X3™ Acetabular inserts.

Indications for Use

The subject devices are single use devices. They are intended for mechanical fixation to their mating hip stems, and can be used in cemented or cementless hip arthroplasty procedures. They can be used with all Howmedica Osteonics C-Taper* hip stems made from Titanium or CoCr alloys. When used as a total hip replacement, they are intended for use only with Howmedica Osteonics polyethylene bearing surfaces.

Indications for Use as a Bipolar

- Femoral head/neck fractures or non-unions,
- Aseptic necrosis of the femoral head,
- Osteo-, rheumatoid, and post traumatic arthritis of the hip with minimal acetabular involvement or distortion.
- Pathological conditions or age considerations that indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum,
- Salvage of failed total hip arthroplasty.

Indications for Use as a Total Hip:

- Painful disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis,
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure,
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results,
- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies in the acetabulum.

* The term "C-Taper" includes both the original C-Taper design, and the modified C-Taper design first introduced on the hip stems found Substantially Equivalent via K982032.

Substantial Equivalence

The features of the new components are substantially equivalent to the predicate devices based on similarities in intended use, materials and design. Mechanical testing demonstrates substantial equivalence of the new components to the predicate devices in regards to mechanical strength. In addition, the intended use, material, manufacturing methods, packaging, and sterilization of the predicate and new components are identical.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2005

Ms. Karen Ariemma
Senior Regulatory Affairs Specialist
Stryker Howmedica Osteonics
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K051588
Trade/Device Name: Line Extension to Biolox® Delta Ceramic Femoral Heads
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: June 13, 2005
Received: June 15, 2005

Dear Ms. Ariemma:

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) 276-0120. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Miriam Provost, Ph.D.
Acting 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): _____

Device Name: Biolox® Delta Ceramic Femoral Heads

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (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)

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

510(k) Number K051588