K073567

Summary of Safety and Effectiveness

MAR 13 2008

Submitter:	Zimmer GmbH Sulzer Allee 8 Winterthur, Switzerland CH - 8404
Contact Person:	Patricia Jenks Specialist, Corporate Regulatory Affairs Telephone: (574) 371-8354 Fax: (574) 372-4605
Alternate Contact:	Natalie Heck Sr. Manager, Regulatory Affairs Telephone: (574) 372-4219 Fax: (574) 372-4605
Date:	March 4, 2008
Trade Name:	*BIOLOX® OPTION** Ceramic Femoral Head System
Common Name:	Ceramic Femoral Head Prosthesis
Classification Name and Reference:	Hip joint metal/ceramic/polymer semiconstrained cemented or nonporous uncemented prosthesis 21 CFR § 888.3353
Predicate Device(s):	DePuy Delta TS (Taper Sleeve) Ceramic Femoral Head, manufactured by DePuy Orthopaedics, Inc., K071830, cleared September 28, 2007
Device Description:	The *BIOLOX OPTION* Ceramic Femoral Head System consist of a ceramic head fabricated from an alumina matrix composite available in diameters of 28, 32, 36, and 40 mm and a titanium adapter for the femoral stem cone with a range of offsets to accommodate various patient anatomies. The system serves as an alternative to both metal and alumina ceramic femoral heads and is for use in both primary and revision total hip arthroplasty.
Intended Use:	The *BIOLOX OPTION* Ceramic Femoral Head System is comprised of modular components

* Trademark of CeramTec AG

	used in primary or revision total hip arthroplasty and indicated for the following: Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, and nonunion of previous fractures of the femur; patients with congenital hip dysplasia, protrusio acetabuli, or slipped capital femoral epiphysis; patients suffering from disability due to previous fusion; patients with previously failed endoprostheses and/or total hip components in the operative extremity; and patients with acute neck fractures.
Comparison to Predicate Device(s):	The *BIOLOX OPTION* Ceramic Femoral Head System is substantially equivalent to the femoral head system listed above as the predicate device. Both the proposed and predicate designs are intended to function as a modular ceramic femoral head component in total hip arthroplasty and are manufactured by CeramTec AG from the same materials.
Performance Data (Nonclinical and/or Clinical):	Non-Clinical Performance and Conclusions: Mechanical testing was performed and results indicate that the *BIOLOX OPTION* Ceramic Femoral Head System is equivalent to devices currently legally marketed, is compatible with Zimmer 12/14 femoral stems and capable of withstanding *in vivo* loading. Clinical Performance and Conclusions: Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Zimmer GmbH
c/o Ms. Natalie Heck
Senior Manager, Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

MAR 13 2008

Re: K073567
Trade/Device Name: BIOLOX OPTION Ceramic Femoral Head System
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or non porous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO
Dated: February 19, 2008
Received: February 21, 2008

Dear Ms. Heck:

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

K073567

Indications for Use

510(k) Number (if known):

Device Name:

*BIOLOX® OPTION** Ceramic Femoral Head System

Indications for Use:

The *BIOLOX OPTION* Ceramic Femoral Head System is comprised of modular components used in primary or revision total hip arthroplasty and indicated for the following:

Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, and nonunion of previous fractures of the femur; patients with congenital hip dysplasia, protrusio acetabuli, or slipped capital femoral epiphysis; patients suffering from disability due to previous fusion; patients with previously failed endoprostheses and/or total hip components in the operative extremity; and patients with acute neck fractures.

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)

Neil R P Ogden for mxm

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

*Trademark of CeramTec AG

510(k) Number K073567