K112463 #1/3

SEP 2 3 2011

510(k) Summary of Safety and Effectiveness

Submitted by:	United Orthopedic Corporation
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Date of Summary:	August 25, 2011
Contact Person	Fang-Yuan Ho Regulation and Document Management
Proprietary Name:	36 mm Ceramic Femoral Head, Delta
Common Name:	Semi-constrained total hip prostheses
Device Classification Name and Reference:	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis under 21CFR 888.3353 This falls under the Orthopedics panel.
Device Class	Class II
Panel Code	Orthopaedics Device
Device Product Code:	LZO, MEH, LPH
Predicate Device:	1. "UNITED" Ceramic Femoral Head, manufactured by United Orthopedic Corporation, K103497, cleared March 04, 2011 2. Smith & Nephew BIOLOX® Delta Ceramic Femoral Heads (K083762, K100412) 3. BIOMET BIOLOX® Delta Ceramic Heads (K042091, K061312, K051411)

Device Description:

"UNITED" 36 mm Ceramic Femoral Head – Delta is an additional size extension to the

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previously cleared "UNITED" Ceramic Femoral Head (K103497). The materials, design, safety and effectiveness of this subject are identical to the previously cleared Ceramic Femoral Head – Delta Components (available in sizes 28 mm and 32 mm), except for its larger diameter (available in sizes 36 mm). 36 mm Ceramic Femoral Head – Delta manufactured from zirconia-toughened alumina ceramic is available in –3, +1, +5 and +9 mm of neck length. This device is intended to articulate against XPE cup liners (K111546) and can be used in conjunction with U2 Acetabular Cups and U2 Hip Stem made of titanium. U2 Acetabular Cups include U2 HA/Ti Plasma Spray Cup (K050262), U2 Ti Plasma Spray Cup (K050262) and U2 Ti Porous Cup (K111546), while U2 Hip Stem include HA/Ti Plasma Spray Stem (K003237), Ti Porous Coated Stem (K003237), Ti Plasma Spray Revision Stem (K062978), Ti Press-fit Stem (K111546) and UTF Stem (K110245). The size extension does not affect the intended use of the device or alter the fundamental scientific technology of the device.

Intended Use

"UNITED" 36 mm Ceramic Femoral Head – Delta is indicated for use in total hip arthroplasty for the following conditions: painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis; correction of functional deformity; treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques; revision procedures where other treatment or devices have failed arthroplasty or other procedure.

Basis for Substantial Equivalence:

The safety and effectiveness of 36 mm Ceramic Femoral Head – Delta are substantially

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equivalent to the previously cleared Ceramic Femoral Head (K103497), except for an extension in the size distribution. The modifications do not change the intended use or fundamental scientific technology. In addition, the subject device is also substantial equivalence to the Smith & Nephew BIOLOX® Delta Ceramic Femoral Heads (K083762, K100412) and BIOMET BIOLOX® Delta Ceramic Heads (K042091, K061312, K051411).

Performance Data:

This 510(k) was prepared in accordance with "Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems". Burst test, fatigue test, burst test for post-fatigue, rotational resistance test and pull-off test. completed as part of the design assurance process demonstrated that this device is safe and effective and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

United Orthopedic Corporation
% Fang-Yuan Ho
Regulatory Affairs Manager
57 park Ave. 2, Sience Park
Hsinchu, China (Taiwan) 300

SEP 23 2011

Re: K112463
Trade/Device Name: 36mm Ceramic Femora Head, Delta
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/ polymer semi-constrained cemented or nonporous uncemented prothesis
Regulatory Class: Class II
Product Code: LZO, MEH, LPH
Dated: August 16, 2011
Received: August 26, 2011

Dear Fang-Yuan Ho:

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

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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,

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

Enclosure

Indication for Use

510 (k) Number (if known): K112463

Device Name: 36 mm Ceramic Femoral Head, Delta

Indications for Use:

This device is indicated for use in total hip arthroplasty for the following conditions: painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis; correction of functional deformity; treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques; revision procedures where other treatment or devices have failed arthroplasty or other procedure.

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)

Michael D. Owens for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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