



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

TGM Medical, Incorporated
% Kellen Hills, Senior Regulatory Consultant
Orchid Design, A Division of Orchid Orthopedic Solutions
4600 E Shelby Drive
Memphis TN 381188

September 9, 2015

Re: K150576

Trade/Device Name: TGM BioloX[®] delta Ceramic 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: July 30, 2015

Received: August 07, 2015

Dear Mr. Hills:

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 (21CFR 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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

Mark N. Melkerson -S

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

Enclosure

Indications for Use

510(k) Number (if known)

K150576

Device Name

TGM BioloX® delta Ceramic Heads

Indications for Use (Describe)

TGM BioloX® delta Ceramic Heads are indicated for use in total hip replacement with cemented or non-cemented femoral and acetabular components of compatible TGM Medical systems in cases of:

- A. Significantly impaired joints resulting from rheumatoid, osteo, and post-traumatic arthritis.
- B. Revision of failed femoral head replacement, cup arthroplasty or other hip procedures.
- C. Proximal femoral fractures.
- D. Avascular necrosis of the femoral head.
- E. Non-union of proximal femoral neck fractures.
- F. Other indications such as congenital dysplasia, arthrodesis conversion, coxa magna, coxa plana, coxa vara, coxa valga, developmental conditions, metabolic and tumorous conditions, osteomalacia, pseudarthrosis conversion, and structural abnormalities.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

[As Required by 21 CFR 807.92]

- (a)(1) Submitted By: TGM Medical, Inc
5145 Golden Foothill Parkway
El Dorado Hills, CA 95762
916-292-8502
- Phone: 916-292-8502
- Date: July 30, 2015
- Contact Persons
Primary: Kellen Hills (Orchid Design Consulting)
Secondary: Gordon Smith (TGM Medical, Inc)
- (a)(2) Proprietary Name: BioloX® delta
Common Name: Ceramic Femoral Head
Classification Name and Reference: 21CFR 888.3353 – Hip joint
metal/ceramic/polymer semi-
constrained cemented or nonporous
uncemented prosthesis
- Product Code: LZO
- (a)(3) Predicate Devices: Biomet BioloX® *delta* Heads (K131684)
Depuy BioloX® *delta* Heads
(K031803/K040644)
TGM Helicon/Zenith Total Hip Systems
(K111472/K121636)
- (a)(4) Device Description:
The BioloX® delta Ceramic Heads are modular femoral components used in hip arthroplasty. The head attaches to a femoral stem via a 12/14 Morse taper and articulates with a polyethylene acetabular component. The ceramic material is Transition-Toughened-Platelet Alumina (TTPA) consisting of 75% Alumina, 24% Zirconia and 1% Platelet. The heads are available in three diameters (28, 32 & 36mm) and a variety of offsets.
- The purpose of this submission is to gain initial marketing authorization in the United States.
- (a)(5) Indications for Use:
BioloX® delta Ceramic Heads are indicated for use in total hip replacement with cemented or non-cemented femoral and acetabular components of compatible TGM Medical systems in cases of:
- A. Significantly impaired joints resulting from rheumatoid, osteo, and post-traumatic arthritis.
 - B. Revision of failed femoral head replacement, cup arthroplasty or other hip procedures.
 - C. Proximal femoral fractures.
 - D. Avascular necrosis of the femoral head.
 - E. Non-union of proximal femoral neck fractures.

- F. Other indications such as congenital dysplasia, arthrodesis conversion, coxa magna, coxa plana, coxa vara, coxa valga, developmental conditions, metabolic and tumorous conditions, osteomalacia, pseudarthrosis conversion, and structural abnormalities.

(a)(6) Comparison of Technological Characteristics:

The subject BioloX® delta Ceramic Heads are being compared to the predicates Biomet BioloX® delta Heads and Depuy BioloX® delta Heads which were cleared under K131684 and K031803/K040644, respectively. The subject and predicate devices are equivalent in terms of intended use, indications for use, material, design and dimensions.

Additional predicates include the TGM Medical Helicon and Zenith Total Hip Systems, K111472 and K121636, respectively. These systems are being used as predicates for their mating components, indications and worst case bench testing constructs.

(b)(1) Non-clinical testing:

Performance testing suggests that the subject BioloX® delta Ceramic Heads perform adequately in burst testing, fatigue testing, post fatigue burst testing, rotational stability and pull-off testing. Previously conducted testing (i.e., proximal and distal fatigue, fretting/corrosion and RoM) were also evaluated using the new ceramic heads and the results were found to be acceptable.

(b)(2) Clinical testing:

Clinical testing was not required to demonstrate substantial equivalence in this premarket notification.

(b)(3) Conclusions:

Based on the information provided in this premarket notification and the details specified in FDA draft guidance document "Ceramic Ball 510(k)s" issued January 10, 1995, we believe that the subject TGM Medical BioloX® delta Ceramic Heads are substantially equivalent to the predicate devices.