K121509

NOV 5 2012

2. 510(k) SUMMARY

Sponsor Name: TGM Medical, Inc.
5145 Golden Hills Parkway, Suite 175
El Dorado Hills, CA 95762

510(k) Contact: Prakash Pai

Phone: (774) 277-1312
prakash.pai63@yahoo.com

Date Prepared: **Revised October 21, 2012**
Trade Name: Treasure Bipolar Head

Common Name: Bipolar head prosthesis for cementless use

Classification Name: Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis (21 CFR 888.3390, Class II device, Product Code KWY).

Device Description:
The TGM Medical, Inc. Treasure Bipolar Head consists of a bipolar femoral head component, locking ring, and a bipolar insert component. The Treasure Bipolar Head is available either fully preassembled, or with the bipolar femoral head and locking ring preassembled and the insert separate. The bipolar femoral head component is manufactured from cobalt chrome alloy (CoCrMo, ASTM F75, ASTM F799, or ASTM F1537). The bipolar head has a highly polished spherical outer surface with a cylindrical bored internal diameter which accepts the polyethylene bipolar insert. The bipolar insert component and locking ring are manufactured from ultra-high molecular weight polyethylene (UHMWPE, ASTM F648). The bipolar insert and locking ring are designed for use with the appropriate size bipolar head component.

Indications for Use:
The Treasure Bipolar Head is intended for use as follows:

A. Fractures of the proximal femur;
B. Nonunions of proximal femoral neck fractures;
C. Aseptic necrosis of the femoral head;
D. Osteo-rheumatoid and post-traumatic arthritis of the hip with minimal distortion of the acetabulum;
E. Salvage of failed total hip arthroplasty.

The Treasure Bipolar Head is intended for cementless use.
The Treasure Bipolar Head is intended for use with the Helicon Hip System.

Substantial Equivalence:

K121509

Technological Characteristics/Substantial Equivalence:
Consensus Orthopedics, Inc. (COI) licensed the previously cleared TaperSet femoral stem (K102399) to TGM Medical, Inc. which was cleared as the Helicon Hip System (K111472). COI has also licensed their previously cleared Bipolar Head (K922560) to TGM for use with Helicon. The components of the new device employ identical materials, design features, packaging and sterilization to the respective COI components and have similar indications. Therefore, the CoCr bipolar head, UHMWPE locking ring, and insert are substantially equivalent to the legally marketed COI predicate devices (Table 2.1).

Table 2.1: Legally marketed devices to which substantial equivalence is claimed:

510(k) Number	Trade Name	510(k) holder	510(k) Release Date
K922560	Consensus Bipolar System	U.S. Medical Products, Inc.	09/11/1992
K102399	Consensus TaperSet Hip System	Consensus Orthopedics, Inc.	12/02/2010
K111472	Helicon Hip System	TGM Medical, Inc.	9/06/2011

Non-Clinical Performance Data:
No new performance data was required for the Treasure Bipolar head.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

TGM Medical, Inc.
% Prakash Pai
5145 Golden Foothill Parkway
Suite 175 & 180
El Dorado Hills, CA 95762 US

November 5, 2012

Re: K121509
Trade/Device Name: Treasure bipolar head, femoral head, treasure bipolar head, insert
Regulation Number: 21 CFR 21 CFR 888.3390
Regulation Name: Hip Joint Femoral (Hemi-Hip) Metal/Polymer Cemented Or Uncemented Prosthesis
Regulatory Class: Class II
Product Code: KWY
Dated: September 21, 2012
Received: September 26, 2012

Dear Prakash Pai:

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,

Peter D. Rumm -S

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

Enclosure

K121509

1. INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: Treasure Bipolar Head

Indications for Use:

The Treasure Bipolar Head is intended for use as follows:

A. Fractures of the proximal femur;
B. Nonunions of proximal femoral neck fractures;
C. Aseptic necrosis of the femoral head;
D. Osteo-rheumatoid and post-traumatic arthritis of the hip with minimal distortion of the acetabulum;
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Prescription Use ___X___ AND/OR Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121509