APR 0 4 2014

BIOMET TRAUMA

510(k) Summary

Preparation Date: 08 January, 2014

Applicant/Sponsor:
Biomet Trauma
56 East Bell Drive
P.O. Box 587
Warsaw, IN 467581
Establishment Registration:

Contact Person:
Gary Baker
Sr. Regulatory Specialist
Tel: (574) 372-1568
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Proprietary Name: TSP Hip Fracture Plating System

Common Name: Proximal Femoral Plating System

Classification Name: 21 CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories.

Product Code(s): JDO, KTT

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

K813554 - Ace/Kyle Captured Hip Screw – Biomet (Formerly DePuy)
K080685 – HipLOC Compression Hip Screw – Biomet
K972629 – TK2 Compression Hip Screw System – Biomet (Formerly DePuy)
K082874 – BioDrive Cannulated Screw System - Biomet
K092078 – OptiLock Periarticular Plating System – Biomet

Device Description:

The TSP Hip Fracture Plating System consists of a series of side specific fracture plates designed to treat femoral neck, intertrochanteric and subtrochanteric fractures.

The TSP Hip Fracture Plating System incorporates fracture plates with multiple cortical screw hole configurations, three 7.5mm telescoping lag screws in lengths ranging from 70mm to 130mm that are inserted into the femoral head and lock into the fracture plate, and 4.5mm cortical screws in lengths ranging from 14mm to 95mm with either locking or non-locking head designs. The plates, lag screws and cortical screws are all made of Ti-6Al-4V titanium alloy with a TiMax® Type II anodized finish.

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Warsaw, IN 46581-0587
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Office: 574.267.6639
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Shipping Address:
56 East Bell Drive
Warsaw, IN 46582

Limited collapse sleeves are also available in 5mm, 10mm, 15mm and 20mm lengths to limit the amount of distraction of the telescoping lag screws.

Indications For Use:

The Biomet Hip Fracture Plating Systems are indicated for use in the open reduction and internal fixation of a wide variety of fractures of the proximal femur: intracapsular fractures and intertrochanteric fractures. Fracture plates with six or more femoral shaft fixation screw holes are also indicated for subtrochanteric fractures as well as proximal femoral osteotomies.

Summary of Technologies:

The TSP Hip Fracture Plating System incorporates fracture plates with multiple cortical screw hole configurations. Telescoping lag screws are inserted into the femoral head and lock into the fracture plate. Cortical screws with either locking or non-locking head designs secure the plate to the lateral femur. Limited collapse sleeves are also available to limit the amount of distraction of the telescoping lag screws.

Non-Clinical Testing:

Testing of the TSP Hip Fracture Plating System included static and cyclic fatigue tests. Additionally, the lag screws and cortical screws were tested for torsional properties, insertion and removal torques and pullout strength. Testing indicated that the system would perform as well as the predicate hip screw systems.

Clinical Testing:

Clinical testing was not determined to be necessary to demonstrate substantial equivalence of the TSP Hip Fracture Plating System to the predicate hip fracture plating systems.

Conclusions:

The TSP Hip Fracture Plating System plates and screws incorporate the same basic design, the same technologies and the same materials as the predicate devices. Based on these similarities, the TSP Hip Fracture Plating System does not raise any new questions of safety or efficacy, and is substantially equivalent to the predicate hip fracture plating systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 4, 2014

Biomet Manufacturing Corporation
Mr. Gary Baker
Senior Regulatory Specialist, Biomet Trauma
56 East Bell Drive
Warsaw, Indiana 46582

Re: K140018
Trade/Device Name: TSP Hip Fracture Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: JDO, KTT
Dated: February 12, 2014
Received: February 14, 2014

Dear Mr. Baker:

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 contact 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Ronald P. Jean -S for

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): K140018

Device Name: TSP Hip Fracture Plating System

Indications For Use:

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Prescription Use ___X___ AND/OR Over-The-Counter Use __NO___
(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)

Elizabeth L. Frank -S

Division of Orthopedic Devices