SECTION 5 – 510(K) SUMMARY

JAN 2 7 2014

Submitted by: Biomet Trauma
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Contact Person: Julie Largent, Regulatory Affairs Specialist

Date Prepared: October 25, 2013

Proprietary Name: Peri-Prosthetic Cabling System

Common Name: Cerclage Cable System

Classification Name: Bone fixation cerclage (21 CFR § 888.3010)

Product Code: JDQ

Predicate Devices: The Peri-Prosthetic Cabling System is substantially equivalent to currently marketed Cable Plate System (K982545).

Device Description: The new Peri-Prosthetic Cabling system consists of cables, crimp lugs (cable sleeves) and associated instrumentation. The cables and crimp lugs are made of cobalt chromium alloy. All cables have a 7x7 strand construction, with the overall cable having a 1.8mm diameter.

Indications for Use: The system is intended for use in femur and tibia fractures, prophylactic banding, trochanteric reattachment, olecranon fractures, patella fractures, ankle fractures, fixation of spiral fractures in conjunction with intramedullary nailing and screwing techniques, sternum fixation after open chest surgery and stabilization of cortical onlay strut grafts.

Technological Characteristics: The technological characteristics of the Peri-Prosthetic Cabling System are similar to the predicate device including design, dimensions and material. The minor technological differences include cable diameter and a spike incorporated on the Peri-Prosthetic Cabling System crimp lug for bone purchase. The

predicate device offers the cables in two diameters, while the Peri-Prosthetic Cabling System offers the cable in one diameter. The cable diameter of the Peri-Prosthetic Cabling System is within the range of the cable diameters of the predicate device.

Summary of Substantial Equivalence:

The Peri-Prosthetic Cabling System is substantially equivalent to the currently marketed device as demonstrated with pre-clinical data including tensile and crimp pull-out testing. Tensile testing demonstrates that the Peri-Prosthetic Cabling System meets or exceeds the requirements of ASTM F2180. The crimp pull-out testing demonstrates that both the Peri-Prosthetic Cabling System and the predicate device meet the minimum requirements for pull out strength. No new issues of safety or efficacy have been raised.

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

January 27, 2014

Biomet, Incorporated
Ms. Julie Largent
Regulatory Affairs Specialist
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581

Re: K133354
Trade/Device Name: Peri-Prosthetic Cabling System
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone fixation cerclage
Regulatory Class: Class II
Product Code: JDQ
Dated: December 20, 2013
Received: December 30, 2013

Dear Ms. Largent:

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,

Vincent D. Devlin -S

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

Enclosure

SECTION 4 – INDICATIONS FOR USE STATEMENT

510(k) Number: K133354

Device Name: **Peri-Prosthetic Cabling System**

Indications For Use:

Intended for use in femur and tibia fractures, prophylactic banding, trochanteric reattachment, olecranon fractures, patella fractures, ankle fractures, fixation of spiral fractures in conjunction with intramedullary nailing and screwing techniques, sternum fixation after open chest surgery and stabilization of cortical onlay strut grafts.

Prescription Use X AND/OR Over-the-Counter _____
(Per 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)

Elizabeth D. Frank -S

Division of Orthopedic Devices

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