DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 30, 2015

Biomet Manufacturing
Ms. Julie Largent
Regulatory Affairs Specialist
P.O. Box 587
56 East Bell Drive
Warsaw, Indiana 46582

Re: K143697
Trade/Device Name: Biomet Proximal Humerus 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: HRS
Dated: February 18, 2015
Received: February 19, 2015

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 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143697 (page 1/1)

Device Name
Biomet Proximal Humerus Plating System

Indications for Use *(Describe)*
The Biomet Proximal Humerus Plating System is indicated for fixation of fractures and fracture dislocations, fusions, osteotomies and non-unions of the humerus, particularly in osteopenic bone.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the Biomet Proximal Humerus Plating System 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

Sponsor:
Biomet Inc.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581
Establishment Registration Number: 1825034

Contact:
Julie Largent
Regulatory Affairs Specialist
305-269-6391

Date:
March 12, 2015

Subject Device:
Trade Name: Biomet Proximal Humerus Plating System
Common Name: Plate, Fixation, Bone

Classification Name:
- HRS - Single/multiple component metallic bone fixation appliances and accessories (21 CFR 888.3030)

Legally marketed devices to which substantial equivalence is claimed:
- ACE Proximal Humerus Plates K955472
- S^3 Shoulder Plating System K060290
- Anatomic Locked Plating System Long Plate Line Extension K101421

Device Description
The Biomet Proximal Humeral Plating System offers two plating families (Low and High) with both left and right configurations in various lengths. Both plating families in the Biomet Proximal Humerus Plating System incorporate the same spatial subchondral support as the Biomet S3 proximal humerus plates (K060290) in the head of the plates. The plates and screws will be manufactured from Titanium Alloy (ASTM F136) and are either type II or color anodized. The system will also include multidirectional screws that are manufactured from Cobalt Chromium (ASTM F1537). The plates are anatomically designed to match the anatomy of the proximal humerus. The system will also include instrumentation to aid the user in alignment and stabilization of fractures to the skeletal system.

Intended Use and Indications for Use

The Intended Use of the Biomet Proximal Humerus Plating System is for internal fixation of humeral fractures. The indications for the Proximal Humerus Plating System are as follows: The Biomet Proximal Humerus Plating System is indicated for fixation of fractures and fracture dislocations, fusions, osteotomies and non-unions of the humerus, particularly in osteopenic bone.

Summary of Technological Characteristics

The rationale for substantial equivalence is based on consideration of the following characteristics:

- **Intended Use:** The Intended Use of the Biomet Proximal Humerus Plating System is the same as to the intended uses cleared in K955472 and K060290 and similar to K101421.
- **Indications for Use:** The indications for the Biomet Proximal Humerus Plating System is similar to and based on the Indications for Use cleared in K955472, K060290, and K101421.
- **Materials:** The Biomet Proximal Humerus Plating System plates are manufactured from Type II anodized Titanium Alloy (Ti-6Al-4V ELI). The locking and non-locking screws included in the system are also manufactured from Titanium Alloy (Ti-6Al-4V ELI ASTM F-136) and are either type II anodized or color anodized. The system also contains multi-directional screws that are manufactured from Cobalt Chromium (ASTM F1537). Titanium alloys as well as implant grade cobalt chromium are commonly used materials in orthopedic implants and are used in predicate devices cleared via K955472 and K101421. The patient contact instrumentation is comprised of stainless steel that meets ASTM F-899.
- **Design Features:** The design features for the Biomet Proximal Humerus Plating System are similar to currently marketed devices K955472, K060290 and K101421. The design differences have not identified any issues that would impact the safety and effectiveness of the devices.
- **Sterilization:** The implants are offered to the user either in the sterile or non-sterile configuration. The non-sterile devices will be required to be steam sterilized by the user prior to use while the sterile implants will be terminally sterilized by gamma irradiation. These sterilization configurations are the same as the predicate devices currently marketed and cleared via K060290 and K101421.

Summary of Performance Data (Nonclinical and/or Clinical)

- Non-Clinical Tests
    - Non-clinical performance testing included axial load construct testing, engineering evaluations and galvanic corrosion assessment to determine substantial equivalence of the Biomet Proximal Humerus Plating System. Results indicate that the subject plating system is substantially equivalent to legally marketed devices offering a reasonable assurance of safety and effectiveness.
- Clinical Tests
    - No clinical tests are provided for basis of substantial equivalence.

Substantial Equivalence Conclusion

The Biomet Proximal Humerus Plating System has shown to be substantially equivalent to the predicate devices. Results of non-clinical tests/engineering justification and the similarities with legally marketed predicated devices indicate the device will perform within the intended uses and no new issues of safety and effectiveness have been raised.