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

Biomet Manufacturing Corporation
Ms. Suzana Otaño
Regulatory Affair Manager
56 East Bell Drive
PO Box 587
Warsaw, Indiana 46581

December 30, 2014

Re: K143188
Trade/Device Name: 3.0mm Biomet Cannulated Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: November 3, 2014
Received: November 5, 2014

Dear Ms. Otaño:

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)*

K143188

Device Name

3.0mm Biomet Cannulated Screw System

Indications for Use *(Describe)*

1. Fixation of small bones, including those in the foot, patella, ankle, wrist and elbow.
2. Arthrodesis of the foot, wrist and elbow.
3. Small and long bone osteotomies.
4. Fracture fixation of small bones, small bone fragments and long bones.

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.

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

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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 3.0mm Biomet Cannulated Screw System 510(k) premarket notification.

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

Contact: Suzana Otaño
Regulatory Affairs Manager, Trauma
Phone: 305-269-6386

Date: December 19, 2014

Subject Device: Trade Name: 3.0mm Biomet Cannulated Screw System
Common Name: Screw, Fixation, Bone
Classification Name:

- HWC– Smooth or Threaded Metallic Bone Fixation Fastener (21 CFR 888.3040)

Legally marketed devices to which substantial equivalence is claimed:

- Biomet Cannulated Screw System - K140891
- BioDrive Cannulated Screw System - K082874
- Synthes Sterile 3.0 mm Cannulated Screw and Threaded Washer - K962823
- FRS Screw – K062352
- Wright Compression Screws (DartFire) – K082320

Device Description

The 3.0mm Biomet Cannulated Screw System consists of bone screws of various lengths and are Ti alloy partially threaded screws with the associated 3.0mm washer. They are offered in both a sterile and non-sterile configuration. The 3.0mm Biomet Cannulated Screw System also contains dimensionally optimized corresponding instruments which are used with the 3.0mm Biomet Cannulated Screws and washers to aid in the alignment and stabilization of fractures to the skeletal system.

Intended Use and Indications for Use

1. Fixation of small bones, including those in the foot, patella, ankle, wrist and elbow.
2. Arthrodesis of the foot, wrist and elbow.
3. Small and long bone osteotomies.
4. Fracture fixation of small bones, small bone fragments and long bones.

Summary of Technological Characteristics

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

- **Materials:** The Biomet Cannulated Screw System screws and washers are fabricated from Ti-6Al-4V alloy per ASTM F136. The materials used in the 3.0mm Biomet Cannulated Screw System are identical to those used in K140891, and similar to those used in K082874, and K962823.

- **Design Features:** The 3.0mm Biomet Cannulated Screws are similar in design and dimension to the Biomet Cannulated Screw System cleared via K140891 and are considered a line extension. The design of the subject device is similar to those cleared in K082874 and K962823.

- **Sterilization:** The sterilization configurations of the 3.0mm Biomet Cannulated Screw System is identical to that of the Biomet Cannulated Screw System cleared via K140891. The sterilization configurations are similar to that of the devices cleared via K082874 and K962823.

Summary of Performance Data (Nonclinical and/or Clinical)

- Non-Clinical Tests
    - Non-clinical performance testing included torsional, axial pullout and insertion/removal torque mechanical tests per ASTM F543. The axial pullout and insertion/removal torque values were equal to or better than the predicate devices. Engineering analysis of the torsional yield strengths demonstrated that the 3.0mm Biomet Cannulated Screws have equal to or better torsional yield strength than the predicate screws including the FRS screw (K062352) and the DartFire screw (K082320). Results of bench testing in conjunction with engineering analysis indicate that the subject screws are substantially equivalent to legally marketed devices offering a reasonable assurance of safety and effectiveness.

- Clinical Tests
    - None provided as a basis for substantial equivalence.

Substantial Equivalence Conclusion

The 3.0mm Biomet Cannulated Screw System is substantially equivalent to the commercially available Biomet Cannulated Screw System cleared via K140891, as well as the devices cleared via K082874, K082320, K062352 and K962823.