



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

October 12, 2016

Biomet Inc.
Ms. Julie Largent
Regulatory Affairs Specialist
56 East Bell Drive
Warsaw, Indiana 46582

Re: K162424

Trade/Device Name: Ulna 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: August 29, 2016

Received: August 30, 2016

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 Parts 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,


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

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

Indications for Use

510(k) Number (if known)

K162424

TBD

Device Name

Ulna Plating System

Indications for Use (Describe)

The System is indicated for fixation of fractures, osteotomies and non-unions of the ulna, 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 Ulna 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: October 5, 2016

Subject Device: Trade Name: Ulna 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:

- Locking Anatomic and Composite Plate System K083843¹
- Distal Volar Radius Plating System K112345

Device Description

The Ulna Plating System is comprised of two new low profile plates anatomically contoured for the ulna, existing screws² and both system specific and general instrumentation. The plates, locking screws and non-locking screws are manufactured from titanium alloy Ti6Al4V ELI per ASTM F136. All the plates are Type II anodized. The plates incorporate both locking and non-locking holes that allow the surgeon to stabilize the fracture by the use of compression plating techniques and then obtain neutralization of the construct with the locking screws. The locking screws construct can protect the compression screws while providing relative stability across extensive comminution of in osteopenic bone. The plate material and the inclusion of both locking and non-locking holes are design features also included in the predicate device cleared in K083843. The plates are designed to accept existing 2.7mm locking screws, 2.7mm non-

¹ K083843 includes two families of plates. The subject device is claiming substantial equivalence to the Locking Composite Plate due to the similar size, shape and function.

² See Section 14 for a listing of existing screws used in the Ulna Plating System.



Ulna Plating System | Traditional 510(k)

locking screws, and 2.7mm multidirectional screws. The non-locking and locking screws are manufactured from Titanium Alloy per ASTM F-136 and are color anodized. The multidirectional screws are manufactured from Cobalt Chromium Alloy per ASTM 1537. The predicate also includes Cobalt Chromium (ASTM F1537) multidirectional screws. The Ulna Plating System will offer the surgeon several system specific instruments as well as various general instruments to facilitate the installation of the implants.

Intended Use and Indications for Use

The System is indicated for fixation of fractures, osteotomies and non-unions of the ulna, 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 is similar to the Intended Use cleared in K083843.
- **Indications for Use:** The Indications for Use is similar to the Indications for Use cleared in K083843.
- **Materials:** The new Ulna Shortening System plates are manufactured from Type II anodized Titanium Alloy (Ti-6Al-4V ELI ASTM F136). The existing 2.7mm locking and non-locking screws included in the system are also manufactured from Titanium Alloy (Ti-6Al-4V ELI ASTM F136) and are either Type II anodized or color anodized. The system also contains existing 2.7mm multi-directional screws that are manufactured from Cobalt Chromium Alloy (ASTM F1537). Titanium alloys as well as implant grade cobalt chromium are commonly used materials in orthopedic implants and are both used in the predicate device cleared via K083843. The patient contact instrumentation is comprised of stainless steel that meets ASTM F-899.
- **Design Features:** The design features for the Ulna Shortening System are similar to those in currently marketed devices cleared K083843. The design differences have not identified any issues that would impact the safety and effectiveness of the devices.
- **Sterilization:** The implants and instruments are offered to the user in the non-sterile configuration. The non-sterile implants and instruments will be required to be steam sterilized by the user prior to use. The non-sterile packaging configuration is the same as the predicate devices currently marketed and cleared via K083843.

Summary of Performance Data (Nonclinical and/or Clinical)

- Non-Clinical Tests
 - Non-clinical performance testing included construct testing as well as 4-point bend testing per ASTM F382 to determine substantial equivalence of the Ulna Plating System. A Galvanic Corrosion engineering evaluation was also completed and was found to meet the acceptance criteria. Results indicate that the subject plating system is substantially equivalent to legally marketed devices.
- Clinical Tests
 - No clinical tests are provided for basis of substantial equivalence.



Ulna Plating System | Traditional 510(k)

Substantial Equivalence Conclusion

The Ulna Plating System has shown to be substantially equivalent to the predicate devices. Results of non-clinical tests/engineering evaluation 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.