

**SECTION 5 – 510(k) SUMMARY****APR – 1 2014**

Submitted by: Biomet Trauma  
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Contact Person: Suzana Otaño, Regulatory Affairs Manager

Date Prepared: December 20, 2013

Proprietary Name: Modified Distal Radius Plating System

Common Name: Plate, Fixation, Bone

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

Predicate Devices: The Modified Distal Radius Plating System is substantially equivalent to currently marketed Distal Volar Radius Plating System (K112345, K050932, K060864).

Device Description: The Modified Distal Radius Plating System consists of Titanium alloy Extra Narrow and Extra Long family of plates utilizing non-locking, locking and variable angle screws manufactured from Titanium alloy and CoCr for bone fixation and the management of fractures and reconstructive surgeries.

Indications for Use: The system is intended for fixation of fractures, malunions and osteotomies involving the distal radius.

Technological  
Characteristics: The technological characteristics of the Modified Distal Radius Plating System are similar to the predicate devices including design, dimensions and material.

Summary of  
Substantial  
Equivalence: The Modified Distal Radius Plating System is substantially equivalent to currently marketed devices as demonstrated with pre-clinical data including axial load construct testing, 4-point bending testing, evaluation of galvanic corrosion potential and multidirectional screw capability. 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

April 1, 2014

Biomet Trauma  
Ms. Suzana Otaño  
Regulatory Affairs Manager  
56 East Bell Drive  
PO Box 587  
Warsaw, Indiana 46581

Re: K133939

Trade/Device Name: Modified Distal Radius 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: January 3, 2014

Received: January 6, 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 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" (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 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,

**Lori A. Wiggins**

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:**      K133939

**Device Name:**      **Modified Distal Radius Plating System**

**Indications For Use:**

The system is intended for fixation of fractures, malunions and osteotomies involving the distal radius.

Prescription Use   **X**    
(Per 21 CFR 801 Subpart D)

AND/OR      Over-the-Counter             
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

**Elizabeth A. Frank -S**

Division of Orthopedic Devices

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