SECTION 5 – 510(K) SUMMARY

Submitted by:	Biomet Trauma 56 East Bell Drive PO Box 587 Warsaw, IN 46581 Phone: (305) 269-6386 Fax: (305) 269-6400
Contact Person:	Suzana Otaño, Global Project Manager, Regulatory Affairs
Date Prepared:	August 27, 2013
Proprietary Name:	Distal Radius Volar Rim Plating System
Common Name:	Plate, Fixation, Bone
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories (21 CFR § 888.3030)
Predicate Devices:	The Distal Radius Volar Rim Plating System is substantially equivalent to currently marketed Distal Volar Radius Plating System (K112345).
Device Description:	The Distal Radius Volar Rim Plating System consists of a series of plates utilizing non-locking, locking and variable angle screws manufactured from Titanium alloy and CoCr used in bone fixation and the management of fractures and reconstructive surgeries in narrow to standard head widths.
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 Distal Radius Volar Rim Plating System are similar to the predicate devices including design, dimensions and material.
Summary of Substantial Equivalence:	The Distal Radius Volar Rim Plating System is substantially equivalent to currently marketed devices as demonstrated with pre-clinical data including axial load construct testing, evaluation of galvanic corrosion potential, tab bending and function. No new issues of safety or efficacy have been raised.

OCT 0 9 2013

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

October 9, 2013

Biomet, Inc.
Ms. Suzana Otaño
Global Project Manager, Regulatory Affairs
P.O. Box 587
Warsaw, Indiana 46581

Re: K132704
Trade/Device Name: Distal Radius Volar Rim 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: LXT
Date: August 27, 2013
Received: August 29, 2013

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,

Erin D Keith

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: K132704

Device Name: **Distal Radius Volar Rim Plating System**

Indications For Use:

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

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 L. Frank -S

Division of Orthopedic Devices

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