

K071325

JUL 26 2007

510(k) Summary

Preparation Date: July 10, 2007

Applicant/Sponsor: Biomet Trauma (formerly known as EBI Trauma)
100 Interpace Parkway
Parsippany, NJ 07054

Contact Person: Debra L. Bing
Director, Regulatory Affairs
Biomet Trauma
973.299.9300

Proprietary Name: Biomet Variable Locking Plate System

Common Name: Metallic bone plates and screws

Classification Name: Single/multiple component metallic bone fixation appliances and accessories,
21 CFR §888.3030

Product Code(s): HRS, HWC

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

EBI Anterior Cervical Plate System (Cyprus)	K060379	EBI, L.P.
IQL Stainless Steel Bone Plates and Screws	K020221	Biomet Orthopedics, Inc.

Device Description: The Biomet Variable Locking Plate System is an internal fixation system comprised of Ti-6Al-4V and consisting of various-sized plates and screws.

Indications for Use: The Biomet Variable Locking Plate System is used for adult or pediatric patients as indicated for pelvic, small and long bone fracture fixation and fixation of bones that have been surgically prepared (osteotomy) for correction of deformity or arthrodesis. Indications for use include internal fixation of the tibia, fibula, femur, metacarpals, metatarsals, humerus, ulna, radius, middle hand and middle foot bones.

Summary of Technologies: The technological characteristics of the Biomet Variable Locking Plate System are the same as, or similar to, the predicate devices.

Non-Clinical Testing: Engineering analyses comparing the Biomet Variable Locking Plate System to a predicate device were conducted to determine substantial equivalence. The results indicated that the Biomet Variable Locking Plate System was functional within its intended use.

Clinical Testing: None provided as a basis for substantial equivalence.

All trademarks are property of Biomet, Inc. unless otherwise noted.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Biomet Trauma
% Ms. Susan Alexander
Senior Regulatory Specialist
P.O. Box 587
Warsaw, Indiana 46581-0587

JUL 26 2007

Re: K071325

Trade/Device Name: Biomet Variable Locking Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances
and accessories
Regulatory Class: II
Product Code: HRS, HWC
Dated: May 9, 2007
Received: May 10, 2007

Dear Ms. Alexander:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); good manufacturing practice requirements as set

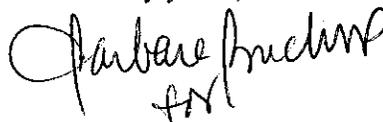
Page 2 - Ms. Susan Alexander

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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is written in a cursive style with a large initial "M".

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071325

Device Name: Biomet Variable Locking Plate System

Indications For Use:

The Biomet Variable Locking Plate System is used for adult or pediatric patients as indicated for pelvic, small and long bone fracture fixation and fixation of bones that have been surgically prepared (osteotomy) for correction of deformity or arthrodesis. Indications for use include internal fixation of the tibia, fibula, femur, metacarpals, metatarsals, humerus, ulna, radius, middle hand and middle foot bones.

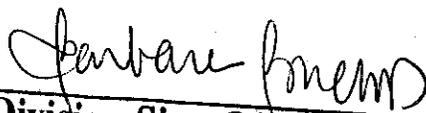
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use NO
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K071325

Page 1 of 1