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510(k) Summary

Preparation Date: April 28, 2008

Applicant/Sponsor: Biomet Trauma (previously EBI, L.P.)
100 Interpace Parkway
Parsippany, NJ 07054
Establishment Registration Number: 1450662

Contact Person: Debra Bing
Director of Regulatory Affairs

Proprietary Name: Lower Extremity External Fixation- Expanded Indications

Common Name: External fixation

Classification Name: KTT- Single, multiple component metallic bone fixation appliances and accessories (888.3030)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

- XFIX® DFS® System (Biomet Trauma)- K040935, K031919, K024129, K023399, K023324, K022319, K021091, K014276, K013540, K013378, K012024, K011697, K000319, K970290, K961433, K953406, K951357
- XFIX® DFS® Rail System (Biomet Trauma)- K021031, K010437, K000083, K991941
- XFIX® Vision (Biomet Trauma)- K040833, K033635, K020141, K014194, K011711, K993886
- XFIX® OptiRom (Biomet Trauma)- K031093, K953406
- Dynafix Diaphyseal/Metaphyseal Correction Systems (Biomet Trauma)- K030372, K024248, K021695, K001358, K953406
- Hoffman® II Micro External Fixation System (Howmedica Osteonics, Inc.)- K052037, K050048

Device Description: The Systems consist of external fixation components and implantable bone screws. The system is utilized in the following manner: bone screws are inserted through the patients skin and soft tissue into bone. The fixator frame of the system is attached the shanks of the bone screws.

Indications for Use: Unilateral external fixation device intended for use in children and adults in the treatment of bone conditions including leg lengthening, osteotomies, arthrodesis, fracture fixation, and other bone conditions amendable to treatment by use of the external fixation modality. Additionally, the Rail System has the additional indication of acute or gradual correction.

Summary of Technologies: The technological characteristics (indications, materials, sizes, dimensions and packaging) are similar to or identical to that of the predicate devices.

Non-Clinical Testing: Non-clinical laboratory testing was previously performed to determine substantial equivalence. The results indicated that the device was functional within its intended use.

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

All trademarks are property of Biomet, Inc. except for:
Hoffman® II Micro External Fixation System is a trademark of Howmedica Osteonics, Inc.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 30 2008

Biomet Trauma
% Biomet Manufacturing Corporation
Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K081244
Trade/Device Name: Lower Extremity External Fixation
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT
Dated: April 28, 2008
Received: May 1, 2008

Dear Ms. Beres:

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined the devices are 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 devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (PMA), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your devices 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 devices comply 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 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 devices as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Mark N Melkerson

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): K081244

Device Name: Lower Extremity External Fixation – Expanded Indications

Indications For Use:
Unilateral external fixation device intended for use in children and adults in the treatment of bone conditions including leg lengthening, osteotomies, arthrodesis, fracture fixation, and other bone conditions amendable to treatment by use of the external fixation modality.

For the XFIX® DFS® Rail System the indications are unilateral external fixation device intended for use in children and adults in the treatment of bone conditions including leg lengthening, osteotomies, arthrodesis, fracture fixation, acute or gradual correction and other bone conditions amendable to treatment by use of the external fixation modality.

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)

Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081244

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