K102843

BIOMET TRAUMA

MAY - 3 2011

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.92.

Preparation Date:	April 4, 2011
Applicant/Sponsor:	Biomet Trauma 100 Interpace Parkway Parsippany, NJ 07054
Contact Person:	Margaret F. Crowe Phone: 973-299-9300 x2260 Fax: 973-257-0232
Trade name:	MAC External Fixation System
Common Name:	External fixation system
Classification Name (Product Code):	KTT/Single/multiple component metallic bone fixation appliances and accessories
Device Panel - Regulation Number:	Orthopedic - 21 CFR 888.3030

Device Description:

The purpose of this submission is to add a Male Adapter Assembly to the previously cleared MAC External Fixation System. The subject MAC Male Adapter Assembly is intended to attach to the existing MAC Module), and allows the MAC to connect to other external fixation components, including: Construx Female Telescoping Arm, Carbon T-clamp, the DFS Angular Hinge and the Carbon Ankle component. These connections allow the surgeon to treat a variety of bone conditions amenable to treatment by use of the external fixation modality.

Indications for Use:

The MAC External Fixation System is a 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 amenable to treatment by use of the external fixation modality. The addition of the MAC Male Adapter does not change the indications for use for the MAC External Fixation System.

Summary of Technologies:

The MAC Male Adapter is similar in terms of material and design features to previously cleared components of the MAC External Fixation System. These components include the

MAC Female Diaphyseal Adapter (previously cleared in premarket notification K021695). This device is intended to connect the MAC Module to other external fixation components. This component is made of similar materials to the MAC Male Adapter, and is assembled in a similar way to the MAC Module.

Substantial Equivalence:

The additional MAC male adapter is substantially equivalent to its predicate devices with respect to intended use and indications, technological characteristics, and principles of operation and do not present any new issues of safety or effectiveness. Examples of predicates include the MAC External Fixation System found substantially equivalent in K021695 and K030372. The MAC System was also found substantially equivalent for use in a pediatric population in K081244. Based upon the mechanical testing, the new component of the MAC External Fixation System is substantially equivalent for its intended use to other external fixation systems currently on the market. The testing provided included:

- Static construct testing of the MAC Male Adapter assembled to aluminum components, and carbon components. The assembled constructs met the pre-established acceptance criteria established by the predicate devices.
- Fatigue construct testing of the MAC Male Adapter assembled to aluminum components, and carbon components to one million cycles. The assembled constructs met the pre-established acceptance criteria established by the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY - 3 2011

Biomet Trauma
% Ms. Margaret Crowe
Regulatory Affairs Project Manager
100 Interpace Parkway
Parsippany, New Jersey 07054

Re: K102843
Trade/Device Name: MAC External Fixation System
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 25, 2011
Received: April 26, 2011

Dear Ms. Crowe:

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.

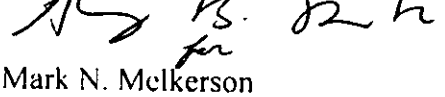
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,



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

Enclosure

Indications for Use

510(k) Number (if known): K102843

Device Name: MAC External Fixation System

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102843