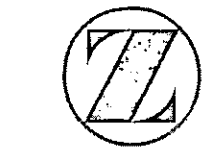

P.O. Box 708
Warsaw, IN 46581-0708
574 267-6131

510(k) Summary

JAN 2 8 2014

Sponsor:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Marcos Velez-Duran President, M Squared Associates, Inc. Telephone: 703-562-9800 (x 206) Fax: 703-562-9797
Date Summary Prepared:	05/15/2013
Trade Name:	*XtraFix*® Small External Fixation System
Common Name:	External Fixation Frame Components
Classification Name and Reference:	21 CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories 21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener
Product Code:	KTT and JDW
Classification Panel:	Orthopedic/87
Predicate Device(s):	-*XtraFix* External Fixation System Line Additions, Zimmer, K113383 cleared on 06/26/2012 -*TransFx* External Fixation System, Zimmer, K984357 cleared on 3/4/1999 and K990848 cleared on 5/17/1999 -External Fixation, Small and Large MR Conditional, Synthes, K031724 cleared on 07/14/2003 and K082650 cleared on 11/18/2008
Purpose and Device Description:	The *XtraFix* Small External Fixation System subject of this 510(k) submission includes the following elements: Clamps (Bar/Pin to Bar/Pin, Integrated Multi-Pin); Bars; and Half Pins. The *XtraFix* Small External Fixation System is designed in such a way that several different types of frames can be assembled. Pins are inserted into bone, and then clamps are assembled to the pins. Bars are

assembled to the clamps and a frame is constructed. After reducing the fracture, all clamps are tightened to hold the frame in place.

Intended Use:

The *XtraFix* Small External Fixation System is indicated for use in construction of an external fixation frame for treatment of appropriately sized long bone (foot, arm, wrist and hand) fractures that require external fixation. Specifically, the system is intended for:

- Stabilization of open or closed fractures, typically in the context of polytrauma or where open or alternative closed treatment is undesirable or otherwise contraindicated;
- Arthrodesis and osteotomies with associated soft tissue problems;
- Stabilization of limbs after removal of total joint arthroplasty for infection or other failure;
- Stabilization of non-unions; and
- Intraoperative temporary stabilization tool to assist with indirect reduction.

Summary of Technological Characteristics:

The subject *XtraFix* Small External Fixation System has the same technological characteristics as the predicate *XtraFix* External Fixation System. The elements are smaller versions of the elements in the larger system and they are manufactured using the same materials. In addition, the *XtraFix* External Fixation System is similar to the Synthes External Fixation System and the *TransFx* External Fixation System.

Performance Data (Nonclinical and/or Clinical):

The *XtraFix* Small External Fixation System was characterized and evaluated according to the requirements outlined in ASTM F1541-02(2007), FDA Guidance Documents: *Standard Specification and Test Methods for External Fixation Devices, FDA Reviewers Guidance Checklist for Orthopedic External Fixation Devices*, and *Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment*. Interconnection strength and system rigidity testing and analyses confirmed that the subject device is substantially equivalent to the predicate devices. In addition, the *XtraFix* Small External Fixation System was found to be MRI Conditional per the FDA Guidance "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment" issued on August 21, 2008. The following results support the MRI Conditional claim:

1) Force generated for worst component in a 3T MRI is 43% the force of gravity;
2) No measurable torque was demonstrated in a 3T static field;
3) Heating was at most 4.7 °C for 15 minutes at a SAR of 3.1 W/kg;
4) Image artifact extended approximately 53-63mm from the device.

Clinical data and conclusions were not needed to show substantial equivalence.

Substantial Equivalence Information:

The *XtraFix* Small External Fixation System is similar to legally marketed devices listed previously in that they share similar indications for use and incorporate similar technological characteristics. All evaluations determined that the *XtraFix* Small External Fixation System is substantially equivalent to the predicate devices.

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

January 28, 2014

Zimmer, Incorporated
% Mr. Romil Sheth
Specialist, Trauma Regulatory Affairs
Zimmer, Incorporated
P.O. Box 780
Warsaw, Indiana 46581

Re: K131413
Trade/Device Name: *XtraFix*® Small External Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT, JDW
Dated: December 23, 2013
Received: December 24, 2013

Dear Mr. Sheth:

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" (21 CFR 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,

Vincent D Devlin -S

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

Enclosure

Indications for Use

510(k) Number (if known):

Device Name:

XtraFix® Small External Fixation System

Indications for Use:

The *XtraFix* Small External Fixation System is indicated for use in construction of an external fixation frame for treatment of appropriately sized long bone (foot, arm, wrist and hand) fractures that require external fixation. Specifically, the system is intended for:

- Stabilization of open or closed fractures, typically in the context of polytrauma or where open or alternative closed treatment is undesirable or otherwise contraindicated;
- Arthrodesis and osteotomies with associated soft tissue problems;
- Stabilization of limbs after removal of total joint arthroplasty for infection or other failure;
- Stabilization of non-unions; and
- Intraoperative temporary stabilization tool to assist with indirect reduction.

Prescription Use _X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (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)

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices