DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 18, 2014

Zimmer, Incorporated
Romil Sheth
Specialist, Trauma Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K141697
Trade/Device Name: Xtrafix® External Fixation System, 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: June 23, 2014
Received: June 24, 2014

Dear Romil 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 Industry and Consumer Education 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 Industry and Consumer Education 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,

Lori A. Wiggins -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141697 (pg 1/2)

Device Name
XtraFix® External Fixation System

Indications for Use *(Describe)*

The XtraFix External Fixation System is indicated for use in construction of an external fixation frame for treatment of long bone (femur, tibia, foot and humerus) and pelvic 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141697 (pg 2/2)

Device Name

XtraFix® Small External Fixation System

Indications for Use *(Describe)*

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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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

510(k) Summary

Sponsor:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Romil Sheth Specialist, Trauma Regulatory Affairs, Zimmer, Inc. Telephone: 574-371-1621 Fax: 574-371-8760
Date Summary Prepared:	06/18/2014
Trade Name:	*1) XtraFix*® External Fixation System (also referred to as *XtraFix* Large System) 2) *XtraFix*® Small External Fixation System (also referred to as *XtraFix* Small System)
Common Name:	External Fixation Frame Components
Classification Name and Reference:	*XtraFix* Large System 21 CFR 888.3030 - Single/multiple component metallic bone fixation appliances and accessories 21 CFR 888.3040 - Smooth or threaded metallic bone fixation fastener *XtraFix* Small System 21 CFR 888.3030 - Single/multiple component metallic bone fixation appliances and accessories
Product Code:	*XtraFix* Large System KTT and JDW *XtraFix* Small System KTT
Classification Panel:	Orthopedic/87

Predicate Device(s):	<u>*XtraFix* Large System</u> -*XtraFix* External Fixation System, Zimmer, K113383 cleared on 06/26/2012 <u>*XtraFix* Small System</u> -*XtraFix* Small External Fixation System, Zimmer, K131413 cleared on 01/28/2014 -*TransFx* External Fixation System, Zimmer, K990848 cleared on 5/17/1999
Purpose and Device Description:	The purpose of this traditional 510(k) is to seek clearance to market the line additions to the *XtraFix* Large and Small Systems. This traditional 510(k) also covers the proposed change to add a MRI conditional symbol on the existing carbon fiber bars in the *XtraFix* Large System so that the *XtraFix* Large System constructs with carbon fiber bars can be used in the MR environment (entirely outside the bore of the MRI scanner). A Bar to Pin, 2D, independent locking clamp and a half pin are being added to the *XtraFix* Large System. A Bar/Pin to Bar/Pin, 2D, independent locking clamp and carbon fiber bars are being added to the *XtraFix* Small System. The *XtraFix* Large and Small Systems include the following elements: clamps, bars and half pins. The *XtraFix* Large and Small Systems are 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:	<u>*XtraFix* Large System</u> The *XtraFix* External Fixation System is indicated for use in construction of an external fixation frame for treatment of long bone (femur, tibia, foot and humerus) and pelvic 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.

<u>*XtraFix* Small System</u>

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 independent locking clamps being added to the *XtraFix* Large and Small Systems are intended to hold half pins and bars. These clamps allow for both their jaws to independently tighten upon the element (half pin/bar) they have grasped by tightening the respective nut. The half pin being added to the *XtraFix* Large System has a 6mm shank/major thread diameter; its overall length is 250mm and it has an 85mm long threaded portion. This half pin is made from 316L stainless steel (per ASTM F138). The bars being added to the *XtraFix* Small System are 6mm in diameter and have lengths ranging from 65mm to 300mm. These bars are made from carbon fiber/epoxy composite material.

Performance Data (Nonclinical and/or Clinical):

The line additions to the *XtraFix* Large and Small Systems have been characterized and evaluated according to the requirements outlined in ASTM F1541-02 (2011) e1 *Standard Specification and Test Methods for External Fixation Devices and FDA Reviewers Guidance Checklist for Orthopedic External Fixation Devices.* Static axial & torsional grip strength testing and the rigidity analyses confirmed that the line additions to the *XtraFix* Large and Small Systems are substantially equivalent to the predicate devices.

In addition, the *XtraFix* Large System with carbon fiber bars 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 MRI conditional claim is supported by the following,
1) Force generated for the device components in a 3T MRI is lesser than the force on the respective components due to gravity;
2) The device components do not experience a measurable torque in a 3T static field;
3) With the worst-case construct placed 50cm away from the center of the magnet of a MR scanner (64 MHz) the heating was at most 4.5 °C following 15 minutes of exposure when scaled to a whole body SAR level of 2.0 W/kg
4) With the worst-case construct placed 50cm away from the center of the magnet of a MR scanner (128 MHz) the heating was at most 2.3 °C following 15 minutes of exposure when scaled to a whole body SAR level of 2.0 W/kg.
5) Largest image artifact did not extend more than 60mm from the device.

Also, the *XtraFix* Small System with carbon fiber bars 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 MRI conditional claim is supported by the following,
1) Force generated for the device components in a 3T MRI is lesser than the force on the respective components due to gravity;
2) The device components do not experience a measurable torque in a 3T static field;
3) With the worst-case construct placed 50cm away from the center of the MR scanner (64 MHz) bore the heating was at most 1.3 °C following 15 minutes of exposure when scaled to a whole body SAR level of 2.0 W/kg.
4) With the worst-case construct placed 50cm away from the center of the MR scanner (128 MHz) bore the heating was at most 3 °C following 15 minutes of exposure when scaled to a whole body SAR level of 2.0 W/kg.
5) Largest image artifact did not extend more than 63mm from the device.

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

Substantial Equivalence Information:	The line additions to the *XtraFix* Large and Small Systems have same/similar indications for use, have same/similar design features, come in same/similar sizes, are made from same/similar material, and are provided non-sterile like their predicate devices. Further, performance testing and engineering rationales included in this submission demonstrate that any differences in technological characteristics do not adversely affect the safety and effectiveness of the line additions to the *XtraFix* Large and Small System. Also, the indications for use, size, shape, materials and sterility of the existing carbon fiber bars in the *XtraFix* Large System to which we are proposing to add a MRI conditional symbol remain unchanged. Further, the MRI related testing and engineering rationales included in this submission demonstrate that using the carbon fiber bars in the MR environment (entirely outside the bore of MRI scanner) do not adversely affect the safety of the *XtraFix* Large System.