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

December 4, 2015

Zimmer, Incorporated
Sujith M. Kallur
Regulatory Affairs Specialist
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K152484
Trade/Device Name: *FastFrame*™ External Fixation System - Distal Radius
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: KTT, JDW
Dated: November 11, 2015
Received: November 12, 2015

Dear Sujith Kallur:

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 Parts 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,

Mark N. Melkerson -S

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)*

K152484

Device Name

FastFrame External Fixation System - Distal Radius

Indications for Use *(Describe)*

The FastFrame External Fixation System - Distal Radius is indicated for use in treatment of appropriately sized long bone (wrist and hand) fractures. 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;
- Stabilization of non-unions; and
- Intraoperative temporary stabilization 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Sponsor:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Sujith M Kallur Regulatory Affairs Specialist, Trauma Regulatory Affairs Telephone: 574-453-6350 Fax: 574-871-8760
Date:	08/28/2015
Trade Name:	*FastFrame*™ External Fixation System – Distal Radius
Common Name:	External Fixation Frame Components
Classification Names and References:	Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Components (KTT) per 21 CFR 888.3030, Single/multiple component metallic bone fixation appliances and accessories and Pin, Fixation, Threaded (JDW) per 21 CFR 888.3040, Smooth or threaded metallic bone fixation fastener
Classification Panel:	Orthopedics/87
Predicate Device(s):	-*XtraFix* Small External Fixation System by Zimmer Inc. K131413, cleared 28-Jan-2014 -*XtraFix* Small External Fixation System by Zimmer Inc. K141697, cleared 18-Sep-2014
Purpose and Device Description:	The purpose of this 510(k) is to obtain marketing clearance for the new device, the *FastFrame* External Fixation System – Distal Radius. The systems consists of fixation half- pins attached to rigid clamps connected by adjustable telescoping tubes (bars) and are intended for use in the treatment of long bone fractures that require external fixation.
Intended Use/Indications for Use:	The *FastFrame* External Fixation System – Distal Radius is indicated for use in treatment of appropriately sized long

bone (wrist and hand) fractures. 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 non-unions; and

- Intraoperative temporary stabilization to assist with indirect reduction.

Comparison to Predicate Device: Both the subject and predicate systems can be used to reduce and fix long bone anatomy of the wrist and hand. Both systems use bars, clamps, and fixation pins to achieve the clinical end result. Both systems allow for length distraction and polyaxial motion between clamp bodies.

The major difference between the subject and predicate systems is that predicate system frame needs to be built intra-operatively. The *FastFrame* External Fixation System contains a frame which comes with clamps and bars (telescoping tubes) pre-assembled, and are not dissassemblable by the end user. The subject *FastFrame* External Fixation System is provided in a sterile kit as compared to the predicate system that is provided non-sterile, and must be steam sterilized prior to use.

Performance Data (Nonclinical and/or Clinical): Non-Clinical Performance and Conclusions:

- **Performance Evaluation –** The mechanical testing confirmed that the subject device performs substantially equivalent in full construct rigidity and interconnection performance as compared to the predicate device. In addition, the *FastFrame* External Fixation System – Distal Radius was found to be MRI Conditional per FDA Guidance "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment" issued on December 11, 2014, ASTM F2052-14, ASTM F2213-06 (2011), ASTM F2182-11a, and ASTM F2119-07 (2013).

Conclusions: The results demonstrate that the device is substantially equivalent to the predicate device.

Clinical Performance and Conclusions:

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