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

Zimmer, Incorporated
Mr. Stephen H. McKelvey
Senior Project Manager, Trauma Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

May 1, 2015

Re: K150818
Trade/Device Name: Versa-Fx Femoral Fixation System, Versa-Fx II Femoral Fixation System, Free-lock Femoral 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, HRS
Dated: March 26, 2015
Received: March 27, 2015

Dear Mr. McKelvey:

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" (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 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)*
K150818

Device Name

Versa-Fx Femoral Fixation System

Indications for Use *(Describe)*

The Versa-Fx Femoral Fixation System may be used for the internal fixation of supracondylar fractures with displaced intra-articular fragments, with vertical intra-articular extension, and in the patient with multiple lower extremity fractures.

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)*

K150818

Device Name

Versa-Fx II Femoral Fixation System

Indications for Use *(Describe)*

Supracondylar: The Versa-Fx II Femoral Fixation System may be used for the internal fixation of supracondylar fractures with displaced intra-articular fragments, with vertical intra-articular extension, and in the patient with multiple lower extremity fractures.

Proximal Femur: The Versa-Fx II Femoral Fixation System may be used for internal fixation of hip fractures with application to intracapsular and intertrochanteric fractures, osteotomies, arthrodeses, and subtrochanteric fractures with extension into the greater trochanter and the piriformis fossa (Winquist Type III comminuted fracture).

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)*

K150818

Device Name

Free-Lock Femoral Fixation System

Indications for Use *(Describe)*

The Free-Lock Femoral Fixation System may be used for internal fixation of hip fractures with application to intracapsular and intertrochanteric fractures, osteotomies, arthrodeses, and subtrochanteric fractures with extension into the greater trochanter and the piriformis fossa (Winquist Type III comminuted fracture).

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:	Stephen H. McKelvey, MA, RAC Senior Project Manager, Regulatory Affairs Telephone: 574-372-4944 Fax: (574) 372-4605
Date:	March 26, 2015
Trade Name:	This is a bundled traditional 510(k). The trade names of the three devices bundled in this submission are: *1) Versa-Fx*® Femoral Fixation System 2) *Versa-Fx*® II Femoral Fixation System 2) *Free-Lock*® Femoral Fixation System
Common Name:	Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component
Classification Names and References:	Single/multiple component metallic bone fixation appliances and accessories (21 CFR § 888.3030, KTT)
Classification Panel:	Orthopedics/87
Predicate Device(s):	Dynamic Condylar Screw (DCS), manufactured by Synthes (K840954, cleared May 11, 1984). *Versa-Fx* Femoral Fixation System, manufactured by Zimmer (K954555, cleared January 26, 1996). Dynamic Hip Screw (DHS), manufactured by Synthes (K791619, cleared August 28, 1979)

Device Description:

Zimmer is requesting clearance for modifications to the *Versa-Fx, Versa-Fx* II and *Free-Lock* Femoral Fixation Systems. The subject devices are similar in that they are used for either supracondylar or proximal femur fracture fixation. The systems contain supracondylar tube/plates with angles of 90° and 95° and/or proximal femur tube/plates with angles from 130° to 150°. These systems share the lag and compression screws.

Intended Use:

***Versa-Fx* Femoral Fixation System**:

The *Versa-Fx* Femoral Fixation System may be used for the internal fixation of supracondylar fractures with displaced intra-articular fragments, with vertical intra-articular extension, and in the patient with multiple lower extremity fractures.

***Versa-Fx* II Femoral Fixation System**:

Supracondylar: The *Versa-Fx* II Femoral Fixation System may be used for the internal fixation of supracondylar fractures with displaced intra-articular fragments, with vertical intra-articular extension, and in the patient with multiple lower extremity fractures.

Proximal Femur: The *Versa-Fx* II Femoral Fixation System may be used for internal fixation of hip fractures with application to intracapsular and intertrochanteric fractures, osteotomies, arthrodeses, and subtrochanteric fractures with extension into the greater trochanter and the piriformis fossa (Winquist Type III comminuted fracture).

***Free-Lock* Femoral Fixation System:**

The Free-Lock Femoral Fixation System may be used for internal fixation of hip fractures with application to intracapsular and intertrochanteric fractures, osteotomies, arthrodeses, and subtrochanteric fractures with extension into the greater trochanter and the piriformis fossa (Winquist Type III comminuted fracture).

Comparison to Predicate Device:

The subject devices incorporate similar or identical materials, similar or identical indications for use, similar or identical sizes of implants, and the same technological characteristics as the predicate devices.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

- **Shelf Life -** Accelerated aging testing conducted shows that the sterile devices included in this submission have a shelf life of 10 years.

- **Biocompatibility** – Biocompatibility testing of the subject devices was conducted per ISO 10993-1 and Good Laboratory Practices (21 CFR 58). All testing passed.

- **Performance Evaluation** – A combination of performance testing (single cycle compression bending strength, fatigue compression bending strength and moment, four-point bend testing) and engineering analyses (beam bending cross sectional analysis) as appropriate demonstrate the subject devices are safe and effective and substantially equivalent to the predicate devices.

  Conclusions: The data presented in this submission demonstrates that the subject devices are substantially equivalent to their respective predicate devices.

Clinical Performance and Conclusions:

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