



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

Zimmer, Incorporated
Mr. Stephen H. McKelvey
Senior Project Manager
P.O. Box 708
Warsaw, Indiana 46581

May 1, 2015

Re: K150626

Trade/Device Name: Rush Medullary Pins
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY
Dated: March 10, 2015
Received: March 11, 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" (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

Indications for Use

Form Approved: OMB No. 0910-0120

Expiration Date: January 31, 2017

See PRA Statement below.

510(k) Number (if known)

Device Name

Rush Medullary Pins

Indications for Use (Describe)

Rush Medullary Pins are indicated for use in fixation of bone fractures, for bone reconstruction, and for skeletal traction in alignment of long bone fracture segments.

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.

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

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 Warsaw, IN 46581-0708
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510(k) Summary

Sponsor: Zimmer, Inc.
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Contact Person: Stephen H. McKelvey
 Senior Project Manager, Trauma Regulatory Affairs
 Telephone: (574) 372-4944
 Fax: (574) 371-8760

Date: March 10, 2015

Trade Name: Rush Medullary Pins

Common Name: Rush Pins

Classification Names and References: Pin, Fixation, Smooth (HTY)
 21 § CFR 888.3040, Smooth or threaded metallic bone fixation fastener

Classification Panel: Orthopedics/87

Predicate Device(s): Ortho Solutions Limited Trauma Implants for Osteosynthesis (including Rush Medullary Pins)
 K110895 - cleared 12/19/2011

Purpose and Device Description: The Rush Medullary Pin is inserted into the medullary canal of long bones to provide internal shaft fracture fixation. It achieves stabilization through the opposition of dynamic forces. The beveled point enables the surgeon to insert from the side of the bone with little chance of driving the pin through the opposing cortex. These devices are made from stainless steel.

Intended Use: Rush Medullary Pins are indicated for use in fixation of bone fractures, for bone reconstruction, and for skeletal traction in alignment of long bone fracture segments.

Comparison to Predicate Device: The subject Rush Medullary Pins are identical in shape, materials, and performance characteristics to the predicate devices. Only the lengths of the subject and predicate devices differ. The subject Rush Medullary Pins with diameters equivalent to the predicate devices but with different lengths were shown to be substantially equivalent to the predicate devices. The indications for use for the subject and predicate devices were shown to be substantially equivalent. The subject device is provided non-sterile as is the predicate device.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

- Biocompatibility - Biocompatibility testing on the Rush Pin material was conducted per ISO 10993-1 and Good Laboratory Practices (21 CFR § 58). All testing passed.
- Performance Evaluation - The subject devices were considered for conformance to material mechanical property standard ISO 5838-1, and were found to be in conformance with the standard. The engineering analysis shows the subject and predicate devices have identical material and cross-sectional geometrical properties, their bending strengths are substantially equivalent.

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

Clinical Performance and Conclusions:

- Clinical data and conclusions were not needed for this submission.