



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

Biomet Incorporated
Ms. Suzana Otano
RA Manager, Trauma
56 East Bell Drive
Warsaw, Indiana 46581

June 10, 2015

Re: K150867
Trade/Device Name: Affixus Tibial Nailing System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB, JDS
Dated: March 27, 2015
Received: April 1, 2015

Dear Ms. Otano:

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

510(k) Number (if known)

K150867

Device Name

Affixus Tibial Nailing System

Indications for Use (Describe)

Indicated for alignment, stabilization, and fixation of fractures caused by trauma or disease, and the fixation of long bones that have been surgically prepared (osteotomy) for correction of deformity and for arthrodesis. This includes transverse fractures, oblique fractures, spiral fractures, segmental fractures, comminuted fractures, open fractures, pathologic fractures, metaphyseal fractures and fractures with bone loss, prophylactic fixation of impending fractures, pseudoarthrosis of the tibial shaft, bone transport, nonunions, malunions, and corrective osteotomies.

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

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the AFFIXUS TIBIAL NAILING SYSTEM 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

Sponsor: Biomet Inc.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581
Establishment Registration Number: 1825034

Contact: Suzana Otaño
Regulatory Manager, Trauma

Date: 27 March 2015

Subject Device: Trade Name: AFFIXUS TIBIAL NAILING SYSTEM
Common Name: INTRAMEDULLARY FIXATION ROD
Classification Name:

- HSB– ROD, FIXATION, INTRAMEDULLARY AND ACCESSORIES (21 CFR 888.3020)

Legally marketed devices to which substantial equivalence is claimed:

- Biomet Phoenix Tibial Locking Nail System [K063570]
- VersaNail Tibial Nail [K032097]
- TriGen Meta-Nail Tibial Nails [K061019]

Device Description

The new Affixus Tibial Nailing System is part of a long bone nailing system that offers an implant design to treat a range of tibial fractures from simple to complex, with versatile locking options. These intramedullary nails offer specific anatomical features designed to aid in insertion, while also offering options to address both proximal and distal fractures. The proximal end of the nail features four screw holes while the distal end contains five. Both the proximal and distal ends offer oblique screw positions to provide maximum fracture stability and/or facilitate capture of distal fragments, as needed. The nails are intended to be used with 4.0 and 5.0mm non-locking screws and the system offers optional end caps that can be inserted into the top of the nail following implantation. The implants shall be offered in a sterile configuration. The system is to be used with a series of instrumentation to aid during the preparation and implantation of the nail, screws and end caps.

Intended Use and Indications for Use

Indicated for alignment, stabilization, and fixation of fractures caused by trauma or disease, and the fixation of long bones that have been surgically prepared (osteotomy) for correction of deformity and for arthrodesis. This includes transverse fractures, oblique fractures, spiral fractures, segmental fractures, comminuted fractures, open fractures, pathologic fractures,

metaphyseal fractures and fractures with bone loss, prophylactic fixation of impending fractures, pseudoarthrosis of the tibial shaft, bone transport, nonunions, malunions, and corrective osteotomies.

Summary of Technological Characteristics

The rationale for substantial equivalence is based on consideration of the following characteristics:

- **Intended Use:** The Affixus Tibial Nailing System and all of the predicate devices are intended for intramedullary fixation of the tibia.
- **Indications for Use:** The Affixus Tibial Nailing System has the same indications for use as the predicate devices.
- **Materials:** The Affixus Tibial Nailing System is fabricated from Ti6Al4V Titanium alloy, the same material used by the predicate devices.
- **Design Features:** The Affixus Tibial Nailing System is similar in overall design, diameters and lengths as the predicate devices.
- **Sterilization:** The sterilization configuration of the Affixus Tibial Nailing System is the same as the predicate devices.

Summary of Performance Data (Nonclinical and/or Clinical)

- Non-Clinical Tests
 - Non-clinical performance testing including static and fatigue construct (nail/screw combination) strength testing was performed and demonstrated that the new Affixus Tibial Nail construct withstood greater static load as well as fatigue load compared to the predicate device.
- Clinical Tests
 - None provided as a basis for substantial equivalence.

Substantial Equivalence Conclusion

The Affixus Tibial Nailing System is substantially equivalent to the commercially available Biomet Phoenix Tibial Nailing System, the Biomet VersaNail Tibial Nailing System and the S&N TriGen Meta-Nail cleared via K063570, K032097 and K061019, respectively.