



December 14, 2018

Biomet Inc.
Dhaval Saraiya
Regulatory Affairs Sr. Specialist
56 East Bell Drive
Warsaw, Indiana 46582

Re: K183162
Trade/Device Name: Affixus Hip Fracture Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB
Dated: November 14, 2018
Received: November 15, 2018

Dear Dhaval Saraiya:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

<https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vesa Vuniqui

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Vuniqui -S
Date: 2018.12.14
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For: 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)

K183162

Device Name

Affixus Hip Fracture Nail System

Indications for Use (Describe)

The Affixus Hip Fracture Nail System is intended to treat stable and unstable proximal fractures of the femur including pertrochanteric fractures, intertrochanteric fractures, high subtrochanteric fractures and combinations of these fractures, including non-union, malunion and tumor resections. The Long Nail system is additionally indicated to treat pertrochanteric fractures associated with shaft fractures, pathologic fractures in osteoporotic bone (including prophylactic use) of the trochanteric and diaphyseal areas, impending pathological fractures, long subtrochanteric fractures, ipsilateral femoral fractures, proximal or distal non-unions, malunions, revision procedures and tumor resections.

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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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 Hip Fracture Nail System - Nails 510(k) premarket notification.

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

Contact Person: Dhaval Saraiya
Senior Regulatory Affairs Specialist
Telephone: (305-269-6386)
Fax: (305-269-6400)

Date: 14th November, 2018

Subject Device: **Trade Name: Affixus Hip Fracture Nail System**
Common Name: Intramedullary Fixation Rod

Classification Name:

- HSB – Rod, Fixation, Intramedullary and accessories
(21 CFR 888.3020)

Predicate Device(s):

K100238	Hip Fracture Nail System	Depuy Orthopaedics, Inc.*
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*The predicate device is included in Biomet's current product portfolio. Biomet acquired DePuy Trauma and as a result of the acquisition of DePuy Trauma, Biomet is now the owner of the predicate device 510(k).

Purpose and Device Description:

The purpose of this submission is to identify the design changes made to the nails to improve the safety and effectiveness of the device.

The Affixus Hip Fracture Nail System consists of intramedullary nails, screws, and end caps to treat fractures in the proximal portion of the femur. All

implants are manufactured from titanium alloy.

**Intended Use and
Indications for Use:**

The Affixus Hip Fracture Nail System is intended to treat stable and unstable proximal fractures of the femur including pertrochanteric fractures, intertrochanteric fractures, high subtrochanteric fractures and combinations of these fractures, including non-union, malunion and tumor resections. The Long Nail system is additionally indicated to treat pertrochanteric fractures associated with shaft fractures, pathologic fractures in osteoporotic bone (including prophylactic use) of the trochanteric and diaphyseal areas, impending pathological fractures, long subtrochanteric fractures, ipsilateral femoral fractures, proximal or distal nonunions, malunions, revision procedures and tumor resections.

**Summary of Technological
Characteristics:**

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

- **Intended Use:** Same as the predicate device
- **Indications for Use:** Same as the predicate device
- **Materials:** Same as the predicate device
- **Design Features:** Same as the predicate device
- **Sterilization:** Same as the predicate device

**Summary of Performance Data
(Nonclinical and/or Clinical)**

- **Non-Clinical Tests:**
 - Study of insertion torque before and after end-of-line cleaning operations
- **Clinical Tests:**
 - N/A

**Substantial Equivalence
Conclusion**

The information provided within this premarket notification demonstrates that the Affixus Hip Fracture Nail System – Nails are substantially equivalent to the predicate device.