



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

Biomet Manufacturing Corporation  
Ms. Patricia Sandborn Beres  
Senior Regulatory Specialist  
56 Bell Drive  
Warsaw, Indiana 46580

October 2, 2015

Re: K151615

Trade/Device Name: TiTHON Staple with OsseoTi Technology

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/multiple component metallic bone fixation appliances and accessories

Regulatory Class: Class II

Product Code: JDR

Dated: September 8, 2015

Received: September 10, 2015

Dear Ms. Beres:

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

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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

Form Approved: OMB No. 0910-0120  
Expiration Date: January 31, 2017  
See PRA Statement below.

## Indications for Use

510(k) Number (if known)

K151615

Device Name

TiTHON Staple with OsseoTi Technology

Indications for Use (Describe)

- Fracture and osteotomy fixation and joint arthrodesis of the hand and foot.
- Fixation of proximal tibial metaphysis osteotomy
- Hand and foot bone fragment and osteotomy fixation and joint arthrodesis
- Fixation of small bone fragments (i.e. small fragments of bone which are not comminuted to the extent to preclude staple placement). These fragments may be located in long bones such as the femur, fibula, and tibia in the lower extremities; the humerus, ulna or radius in the upper extremities; the clavicle and ribs; and in flat bone such as the pelvis, scapula and sternum.

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 **TiTHON Staple with OsseoTi Technology** 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:** Patricia S. Beres  
Senior Regulatory Specialist  
(574) 257-6639 extension 1278

**Date:** September 29, 2015

**Subject Device:** Trade Name: TiTHON Staple with OsseoTi Technology  
Common Name: Bone Staple

Classification Name:

- JDR– Staple, Fixation, Bone (21 CFR888.3030)

**Legally marketed devices to which substantial equivalence is claimed:**

- Speed™, Speed Shift™, Speed Titan™, Speed Arc™ – Biomedical Enterprises, Inc. – K142292

### Device Description

The TiTHON Staples with OsseoTi Technology are long-term fixation staple implants. TiTHON Staples are available in widths of 15, 20 and 25mm, with leg lengths of 7, 10, 15, 20 and 20mm. OsseoTi is a porous metal construct made of a Ti-6Al-4V alloy. The porous architecture mimics the porous structure of human cancellous bone.

### Intended Use and Indications for Use

The TiTHON OsseoTi Staple indications for use are:

- Fracture and osteotomy fixation and joint arthrodesis of the hand and foot.
- Fixation of proximal tibial metaphysis osteotomy
- Hand and foot bone fragment and osteotomy fixation and joint arthrodesis
- Fixation of small bone fragments (i.e. small fragments of bone which are not comminuted to the extent to preclude staple placement). These fragments may be located in long bones such as the femur, fibula, and tibia in the lower extremities; the humerus, ulna or radius in the upper extremities; the clavicle and ribs; and in flat bone such as the pelvis, scapula and sternum.

**Summary of Technological Characteristics**

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

- **Intended Use:** The subject device and the predicate device are both intended for bone fixation
- **Indications for Use:** The subject device and the predicate have identical indications for use
- **Materials:** Both devices are manufactured from titanium alloy
- **Design Features:** The subject device has similar design features to that of the predicate
- **Sterilization:** Both devices are provided sterile by gamma irradiation

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

- Non-Clinical Tests
  - Mechanical testing has been performed in keeping with ASTM F564 – Standard Specification and Test Methods for Metallic Bone Staples
- Clinical Tests
  - No clinical testing was provided to establish substantial equivalence

**Substantial Equivalence Conclusion**

The proposed device has similar technological characteristics to the predicate, and the information provided demonstrates that any differences do not raise new questions of safety and effectiveness and that the proposed device is at least as safe and effective as the legally marketed predicate device.