



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Biomet Microfixation
Ms. Lauren Jasper
Global Regulatory Affairs Specialist
1520 Tradeport Drive
Jacksonville, Florida 32218

May 26, 2015

Re: K151173

Trade/Device Name: Biomet Microfixation RibFix Blu Thoracic Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: April 30, 2015
Received: May 1, 2015

Dear Ms. Jasper:

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): K151173

Device Name: Biomet Microfixation RibFix Blu Thoracic Fixation System

Indications for Use: The Biomet Microfixation Thoracic Fixation System is indicated for use in the stabilization and fixation of fractures in the chest wall including sternal reconstructive surgical procedures, trauma, or planned osteotomies. The system may be used in normal and poor bone to promote union.

Prescription Use xx
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



510(k) Summary

Prepared April 30, 2015

Submitter: Biomet Microfixation
1520 Tradeport Drive
Jacksonville, FL 32218

Contact: Lauren Jasper, Senior Regulatory Affairs Specialist
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Device Name: Biomet Microfixation RibFix Blu Thoracic Fixation System

Common or Usual Name: Bone Screw

Classification Name: Screw, Fixation, Bone

Device Classification:

Product Code	Classification Name	Device Classification	Regulation Number	Regulation Description
HWC	Screw, Fixation, Bone	2	888.3040	Smooth or threaded metallic bone fixation fastener

Indications for Use: The Biomet Microfixation Thoracic Fixation System is indicated for use in the stabilization and fixation of fractures in the chest wall including sternal reconstructive surgical procedures, trauma, or planned osteotomies. The system may be used in normal and poor bone to promote union.

Contraindications: 1. Spanning a midline sternotomy; 2. Active infection; 3. Foreign body sensitivity, where material sensitivity is suspected, testing is to be completed prior to implantation; 4. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.

Device Description: The Biomet Microfixation RibFix Blu Thoracic Fixation System is composed of metallic locking screws that are utilized with previously cleared metallic locking bone plates. These devices provide rigid fixation of fractures and osteotomies of the chest wall and sternum. The locking screws are offered in two diameters, 2.4mm and 2.7mm. The 2.4mm diameter screws are offered with two tip designs, self-drilling and self-tapping, and range in lengths from 7mm to 16mm. The 2.7mm diameter screws are offered with a self-tapping tip design and range in lengths from 7mm to 16mm. The locking screws are manufactured from Titanium Alloy (Ti-6Al-4V).

Predicate Devices:

K142823, Biomet Microfixation Thoracic Fixation System

The similarities of the new thoracic fixation device to the predicate device are as follows:

- The indications for use are identical to that of the predicate device.
- Both systems leverage rigid fixation technology through the use of locking plates and locking screws.
- Locking plates and screws are manufactured out of the same materials as the predicate devices.
- Locking screw self-drilling tip geometry is identical to predicate screw design. There are no changes to material, thread design, or manufacturing processes from the predicate devices.
- There are no changes to sterilization methods; subject and predicate devices are sold non-sterile and are intended to be sterilized by the user prior to implantation.

The changes proposed by this new thoracic fixation device are as follows:

- The addition of a self-tapping screw in the 2.4mm diameter (the predicate device only features a self-drilling tip in the 2.4mm diameter). The predicate device utilizes a self-tapping screw design only in the 2.7mm diameter.
- The addition of the shorter 7mm length screw. Predicate device featured a shortest length of 8mm. As a result the IFU will be updated to reference this additional screw length.
- Screw lengths from 8mm to 16mm of both the self-drilling 2.4mm and self-tapping 2.7mm diameter are identical to predicate screws, except they have been given a new part number to coordinate with their system.

	Subject Device	Predicate Device
Minimum Length	7mm	8mm
Maximum Length	16mm	20mm
Diameter	2.4mm and 2.7mm	2.4mm and 2.7mm
Tip Design	Primary (2.4mm): Self-Drilling and Self-Tapping Emergency (2.7mm): Self-Tapping	Primary (2.4mm): Self-Drilling Emergency (2.7mm): Self-Tapping

Non-Clinical Performance Data: Non-clinical testing was not necessary for the determination of substantial equivalence.

Clinical Performance Data: Clinical testing was not necessary for the determination of substantial equivalence.

Sterilization Information: The implants are provided non-sterile to be sterilized by the end user.

Substantial Equivalence: The proposed devices have the same indications for use as the predicate devices. The submission demonstrates that (1) any differences in technological characteristics of the predicates do not raise any new questions of safety and efficacy and (2) the proposed devices are at least as safe and effective as the predicates. It is concluded that the information included in this summary supports substantial equivalence.