December 9, 2016

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

Re: K162974
Trade/Device Name: Biomet Microfixation Ribfix Blu Thoracic Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: October 24, 2016
Received: October 25, 2016

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" (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

Sincerely,

Vincent J. Devlin -S
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):

Device Name: Biomet Microfixation RibFix Blu Thoracic Fixation System

Indications for Use: The Biomet Microfixation RibFix Blu 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____ AND/OR Over-The-Counter Use _______
(Part 21 CFR 801 Subpart D) (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 October 24, 2016

Submitter: Biomet Microfixation
1520 Tradeport Drive
Jacksonville, FL 32218

Contact: Lauren Jasper, Senior Regulatory Affairs Specialist
lauren.jasper@zimmerbiomet.com
Telephone: (904) 741-9259
Fax: (904) 741-9425

Device Name: Biomet Microfixation RibFix Blu Thoracic Fixation System
Common or Usual Name: Bone Plate and Bone Screw
Classification Name: Plate, Fixation, Bone and Screw, Fixation, Bone

Device Classification: Plate, Fixation, Bone and Screw, Fixation, Bone

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Device Name</th>
<th>Device Classification</th>
<th>Regulation Number</th>
<th>Regulation Description</th>
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<tr>
<td>HRS</td>
<td>Plate, Fixation, Bone</td>
<td>2</td>
<td>888.3030</td>
<td>Single/multiple component metallic bone fixation appliances and accessories</td>
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<tr>
<td>HWC</td>
<td>Screw, Fixation, Bone</td>
<td>2</td>
<td>888.3040</td>
<td>Smooth or threaded metallic bone fixation fastener</td>
</tr>
</tbody>
</table>

Indications for Use: The Biomet Microfixation RibFix Blu 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 bone plates and locking screws that provide rigid fixation to fractures and osteotomies of the chest wall. These implants are available in multiple sizes and manufactured from Commercially Pure Titanium and Titanium Alloy (Ti-6Al-4V).
Predicate Devices:
K152253, Biomet Microfixation RibFix Blu Thoracic Fixation System

The similarities of the subject devices to the predicate devices are as follows:
- The indications for use and contraindications are identical to that of the predicate device.
- The design of the subject devices is equivalent to the predicate devices.
- The sterilization method (steam sterilization) of the subject devices is identical to the predicate devices.
- The materials of the subject devices are identical to the predicate devices.

The changes proposed by this Special 510K are to update various sections of the Package Insert to provide additional information to users.

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.