



August 2, 2016

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

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

Re: K161896

Trade/Device Name: Biomet Microfixation Sternal Closure 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

Dated: July 6, 2016

Received: July 11, 2016

Dear Lauren 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 (Parts 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,

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): K161896

Device Name: Biomet Microfixation Sternal Closure System

Indications for Use: The Biomet Microfixation Sternal Closure System is intended for use in the stabilization and fixation of fractures of the anterior chest wall including sternal fixation following sternotomy and sternal reconstructive surgical procedures, to promote fusion. The Biomet Microfixation Sternal Closure System is intended for use in patients with normal and poor bone quality.

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)

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510(k) Summary

Prepared July 6, 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 Sternal Closure System

Common or Usual Name: Bone Plate

Classification Name: Plate, Fixation, Bone

Device Classification:

Product Code	Classification Name	Device Classification	Regulation Number	Regulation Description
HRS	Plate, Fixation, Bone	2	888.3030	Single/multiple component metallic bone fixation appliances and accessories

Indications for Use: The Biomet Microfixation Sternal Closure System is intended for use in the stabilization and fixation of fractures of the anterior chest wall including sternal fixation following sternotomy and sternal reconstructive surgical procedures, to promote fusion. The Biomet Microfixation Sternal Closure System is intended for use in patients with normal and poor bone quality.

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

Device Description: The Biomet Microfixation Sternal Closure System contains a variety of plates and 2.4mm and 2.7mm diameter screws with a minimum length of 8mm and a maximum length of 20mm. The tip of the 2.4mm screw is designed to be self-drilling so that a predrilled hole is not required. There are threaded features on both the plates and screws to allow for the screw to be locked into the plate when fully seated. The plates are manufactured from Commercially Pure Titanium (conforming to ASTM F67) and the screws are manufactured from Titanium Alloy (Ti-6Al-4V conforming to ASTM F136). The devices are sold non-sterile and intended to be sterilized by the user prior to implantation.

Predicate Devices:

K121302, Biomet Microfixation Sternal Closure 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 equivalent to the predicate devices.
- The materials of the subject devices are equivalent 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.