



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

November 3, 2015

Re: K151019

Trade/Device Name: Sternalock® 360 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: September 17, 2015

Received: September 18, 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 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 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: K151019

**Device Name:** SternaLock® 360 Sternal Closure System

**Indications for Use:** The SternaLock® 360 Sternal Closure System is intended for use in the stabilization and fixation of fractures of the sternum including sternal fixation following sternotomy and sternal reconstructive surgical procedures, to promote fusion. The system is intended for use in patients with normal and/or 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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



## 510(k) Summary

Prepared October 29, 2015

**Submitter:** Biomet Microfixation  
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Jacksonville, FL 32218

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**Device Name:** SternaLock® 360 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 SternaLock® 360 Sternal Closure System is intended for use in the stabilization and fixation of fractures of the sternum including sternal fixation following sternotomy and sternal reconstructive surgical procedures, to promote fusion. The system is intended for use in patients with normal and/or 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 SternaLock® 360 Sternal Closure System is comprised of rigid fixation and cerclage technologies to approximate the sternal halves, provide bone compression, and rigidly fixate bone in one device. The cerclage aids in distributing forces around the sternal bone as well as reducing loss of fixation due to cut-through in bone. Implantable components include a metallic plate pre-assembled to a polymer-coated metallic band; the plate is rigidly fixated to bone through locking screws. The SternaLock® 360 plates are manufactured from

Commercially Pure Titanium; the band is manufactured from Commercially Pure Titanium and coated with Parylene-C; the band locking mechanism is manufactured from Titanium Alloy (Ti-6Al-4V); the locking screws are manufactured from Titanium Alloy (Ti-6Al-4V); and the needle (not implantable) is manufactured from Stainless Steel.

**Predicate Devices:**

K121302, Biomet Microfixation Sternal Closure System

**Similarities to Predicate Devices:**

The similarities of the new sternal closure device to the predicate device are as follows:

- The indications for use are similar 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 plate geometry is similar to the plates previously cleared in the predicate system. Both systems offer a box and X-shape design.
- Locking screw geometry is identical to predicate screw design. There are no changes to material, design, or manufacturing processes from the predicate device. There are no additional lengths of screws offered outside the lengths previously cleared in the predicate system.

**Differences to Predicate Devices:**

The changes proposed by this new sternal closure device are as follows:

- The proposed device is designed to approximate, compress, and fixate sternal bone after a sternotomy or through reconstruction.
- The polymer coating used in the cerclage band design is an additional material, compared to the predicate device.
- The addition of a needle attached to the end of the band to allow the device to be wrapped around or through the sternal bone. The needle is manufactured from stainless steel and is intended to be cut off after use and prior to tensioning the device.
- Device-specific tensioning instrumentation to be offered single-use pre-assembled to the implants to aid in implantation of the device.
- Device sterilization: proposed device is offered sterile via exposure to Ethylene Oxide gas. The predicate device is offered non-sterile and intended to be sterilized by the user prior to implantation.

**Non-Clinical Performance Data:** A single SternaLock® 360 banded-box plate was compared to a single SternaLock® Blu box-shape plate in both static and fatigue testing. A recommended configuration for SternaLock® 360 (banded-box, banded-X, banded-box) was compared to a recommended configuration for SternaLock® Blu (L-shape, X-shape, X-shape) in both static and fatigue testing. All non-clinical performance testing passed according to the acceptance criteria

and the proposed device was found to be statistically equivalent or stronger in all testing than the predicate device. Testing was conducted as follows:

- Single Implant Static Testing
- Single Implant Fatigue Testing
- 3-Implant Construct Static Testing
- 3-Implant Construct Fatigue Testing
- MR Compatibility Testing

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

**Sterilization Information:** The implants are provided sterile by the manufacturer; sterilization method is exposure to Ethylene Oxide gas. Implants are single use and cannot be re-sterilized by the user.

**Substantial Equivalence:** The SternaLock® 360 Sternal Closure System utilizes similar locking plate and locking screw technology as the predicate device. Testing identified in this summary has passed all acceptance criteria and the proposed devices are equivalent or better than predicate devices, where applicable. Indications for use of the predicate and proposed devices are similar. It is therefore concluded that the proposed device is considered substantially equivalent to the predicate device.