DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

December 10,2015

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

Re: K152326
Trade/Device Name: Biomet Microfixation Omnimax Mmf System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: JEY, DZL
Dated: November 13, 2015
Received: November 16, 2015

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 (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 http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K152326

Device Name: Biomet Microfixation OmniMax MMF System

Indications for Use: The Biomet Microfixation OmniMax MMF System is indicated for temporary stabilization of mandibular and maxillary fractures to maintain proper occlusion during surgery and for post-operative fracture healing in adults and adolescents (age 12 and older) in whom permanent teeth have erupted.

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)

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510(k) Summary – K152326

Prepared December 10, 2015

Submitter: Biomet Microfixation
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Contact: Lauren Jasper, Senior Regulatory Affairs Specialist
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Device Name: Biomet Microfixation OmniMax MMF System

Device Classification:
Primary Regulation:

Product Code	Device Name	Device Classification	Regulation Number	Regulation Description
JEY	Plate, Bone	2	872.4760	Bone Plate

Secondary Product Code:

Product Code	Device Name	Device Classification
DZL	Screw, Fixation, Intraosseous	2

Indications for Use: The Biomet Microfixation OmniMax MMF System is indicated for temporary stabilization of mandibular and maxillary fractures to maintain proper occlusion during surgery and for post-operative fracture healing in adults and adolescents (age 12 and older) in whom permanent teeth have erupted.

Contraindications: 1. Patients with mental or neurological conditions who are unwilling or incapable of following postoperative care instructions; 2. Patients with limited blood supply, insufficient quantity or quality of bone; 3. Foreign body sensitivity; where material sensitivity is suspected, testing is to be completed prior to implantation; 4. Severely comminuted fractures or unstable fractures; 5. Active or latent infection; 6. Patients in whom damage to un-erupted permanent teeth is anticipated.

Device Description: The Biomet Microfixation OmniMax MMF System is composed of metallic plates (arch bars) and locking screws that provide temporary stabilization of mandibular and maxillary bone during fracture healing and/or temporarily maintain a stable occlusion during surgery. Mandibular and Maxillary Fixation (MMF) is achieved through application of fixation plates and locking screws to bone; wire or elastics are then secured around hooks. The arch bar

plate is manufactured from Commercially Pure Titanium; the locking screws are manufactured from Titanium Alloy (Ti-6Al-4V); and wires (if used) are manufactured from Stainless Steel.

Predicate Devices:
K143336, Biomet Microfixation OmniMax MMF System

Similarities to Predicate Devices: The predicate and subject devices are metallic implants intended to be used for the stabilization of mandibular and maxillary fractures. The indications for use are identical for the predicate and subject devices. All implant systems consist of plates and locking screws to achieve a stable occlusion during fracture healing or surgery. The predicate and subject devices are manufactured from Commercially Pure Titanium and Titanium Alloy (Ti-6Al-4V). There are no changes to the stainless steel wires that may be used to achieve the MMF closure.

Differences to Predicate Devices: The subject devices are considered MR Conditional per the compatibility restrictions found in the devices' instructions for use.

Non-Clinical Performance Data: MRI simulation and physical testing were performed according to standards ASTM F2052, ASTM F2213, ASTM F2119, and ASTM F2182 to support the MR Conditional labeling.

Modeling and Simulation Testing: This test was conducted to determine the worst-case locations for heating on the implant models at two different resonance frequencies. The results of this testing indicated that the worst-case locations were the ends of the bars and the tips of the screws.
Physical Implant Testing: Using the worst-case heating locations determined during modeling and simulation testing (described above), actual heating was measured in the 1.5T and 3.0T environments; additionally, observed artifact and displacement were also measured in the 1.5T and 3.0T environments.

The completion of testing described above resulted in MR Conditional labeling and demonstrated that a patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5T and 3.0T
- Maximum spatial gradient field of 3,000 gauss/cm (30 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2.0 W/kg (Normal Operating Mode)

Under these scan conditions, the OmniMax MMF System is expected to product a maximum temperature rise of less than 6°C after 15 minutes of continuous scanning. Further, the image artifact caused by the device extends approximately 1.4cm from the device when imaged with a gradient echo pulse sequence and a 3.0T MRI System.

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 Biomet Microfixation OmniMax MMF System has the same indications for use as the predicate devices and both systems feature the same part numbers with the same designs and materials. Testing identified in this summary has determined these devices can be safely used in the MRI environment and may be labeled as MR Conditional. It is concluded that the information included in this summary supports substantial equivalence.

	Subject Device: Biomet Microfixation OmniMax MMF System	**Primary Predicate: Biomet Microfixation OmniMax MMF System (K143336)**
Principle of Operation	No change from predicate device	Metallic implants for the temporary stabilization of mandibular and maxillary bone during fracture healing and/or temporarily maintain a stable occlusion during surgery Mandibular and Maxillary Fixation (MMF) is achieved through application of fixation plates and locking screws to bone; wire or elastics are then secured around hooks
Indications for Use	No change from predicate device	The Biomet Microfixation OmniMax MMF System is indicated for temporary stabilization of mandibular and maxillary fractures to maintain proper occlusion during surgery and for post-operative fracture healing in adults and adolescents (age 12 and older) in whom permanent teeth have erupted.
Components	No change from predicate device	Fixation Plate (Arch Bar), Locking Screws
Plate Geometry	No change from predicate device	Design: Plate with an in-plane bend and 12 slots to accept screws and 12 hooks
Screw Geometry	No change from predicate device	Design: Self-drilling screws Diameter: 2.0mm Length: minimum 7mm, maximum 11mm
Material	No change from predicate device	Plates: Commercially Pure Titanium Screws: Titanium Alloy, Ti-6Al-4V Wires: Stainless Steel
Sterility	No change from predicate device	Non-sterile to be sterilized by the end user
MRI Safety	MR Conditional	Not evaluated

Conclusion: There are no changes from the predicate device regarding the principles of operation, indications for use, components, plate geometry, screw geometry, material, and sterility. The completion of the non-clinical testing described above resulted in MR Conditional labeling and demonstrated that a patient with this device can be safely scanned in an MR system meeting the conditions described in the Instructions for Use included in the package of the device. Upon consideration of this information, it is determined that the subject device is substantially equivalent to the declared predicate device.