August 05, 2021

Biomet Microfixation
Lauren Jasper
Regulatory Affairs Project Manager
1520 Tradeport Drive
Jacksonville, Florida 32218

Re: K202969
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: May 6, 2021
Received: May 7, 2021

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Andrew Steen
Assistant Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K202969

Device Name
Biomet Microfixation OmniMax MMF System

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Prepared August 4, 2021

Submitter: Biomet Microfixation
1520 Tradeport Drive
Jacksonville, FL 32218 USA

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

Device Name: Biomet Microfixation OmniMax MMF System

Common or Usual Name: Bone Plate

Primary Classification Name: Bone Plate

Primary Device Classification:

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

Secondary Device Classification:

Product Code	Device Name	Device Classification	Regulation Number	Regulation Description
DZL	Screw, Fixation, Intraosseous	2	872.4880	Intraosseous fixation screw or wire

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: Biomet Microfixation manufactures and distributes the Biomet Microfixation OmniMax MMF System. 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 OmniMax MMF system includes a fixation plate (also known as an arch bar) that has an in-plane bend to provide an initial approximation of mandibular and maxillary anatomy. The plate also features slots for locking screw fixation. These slots allow for a maximum of 12 fixation points in the bone as well as screw placement variation within the slot to avoid tooth roots. The OmniMax locking screws are 2.0mm in diameter and vary in length from 7mm to 11mm. The screw head also features a low-profile design to minimize irritation and palpability.

Substantial Equivalence:

	Subject Device: Biomet Microfixation OmniMax MMF System (K202969)	**Primary Predicate: Biomet Microfixation OmniMax MMF System (K152326)**
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

	Subject Device: Biomet Microfixation OmniMax MMF System (K202969)	**Primary Predicate: Biomet Microfixation OmniMax MMF System (K152326)**
User cleaning	Add cleaning instructions for the processing of reusable instruments and new/uncompromised implants.	Not evaluated
Sterility	No change from predicate device	Non-sterile to be sterilized by the end user
MRI Safety	No change from predicate device	MR Conditional
Biocompatibility	Update manufacturing process flow and provide biocompatibility assessment of those updates.	Not evaluated

Non-Clinical Performance Data: Validation testing to support the cleaning process were submitted in this premarket notification submission for a determination of substantial equivalence. Testing passed all acceptance criteria. Cleaning validation meets the standards outlined in FDA guidance document *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling.*

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

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

Biocompatibility Information: Manufacturing process flow updates were provided in this premarket notification submission for a determination of substantial equivalence. Process monitoring results and review of contact materials has passed acceptance criteria established by the predicate device per ISO 10993-1.

Conclusion: The submission demonstrates that: (1) any differences in technological characteristics of the predicates do not raise any new questions of substantial equivalence and (2) the proposed devices are substantially equivalent to the primary predicate.