Attachment 5 – Revised 510(k) Summary

510(k) Summary

SEP 2 1 2012

510(k) Number:	K121589
Date Prepared:	July 23, 2012
Submitter:	Biomet Microfixation 1520 Tradeport Drive Jacksonville, FL 32218
Contact:	Lauren Jasper, Regulatory Affairs Specialist Lauren.Jasper@biomet.com Telephone: 904-741-9259 Fax: 904-741-9425

Common of Usual Name:	Bone Plate	or	Bone Screw
Classification Name:	Plate, Fixation, Bone		Screw, Fixation, Bone
Device Classification:	Class II		Class II
Device Product Code:	76 JEY (21 CFR 872.4760)		87 HWC (21 CFR 888.3040)

Device Name: Biomet Microfixation Facial Plating System

Intended Use:
These devices are implantable bone plates and bone screws for facial procedures including:

1. Fractures
2. Osteotomies
3. Reconstructive procedures
4. Revision procedures where other treatments or devices have failed

Contraindications:

1. Active infection
2. Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation.
3. Patients with limited blood supply, insufficient quantity or quality of bone, or latent infection.
4. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.

Possible Risks:

1. Poor bone formation, Osteoporosis, Osteolysis, Osteomyelitis, inhibited revascularization, or infection can cause loosening, bending, cracking or fracture of the device.
2. Nonunion or delayed union, which may lead to breakage of the implant.
3. Migration, bending, fracture or loosening of the implant.
4. Metal sensitivity or allergic reaction to a foreign body.

5. Decrease in bone density due to stress shielding.
6. Pain, discomfort, abnormal sensation, or palpability due to the presence of the device.
7. Increased fibrous tissue response around the fracture site and/or the implant.
8. Necrosis of bone.
9. Inadequate healing.

Description:
The Biomet Microfixation Facial Plating System is comprised of a variety of titanium plates, meshes, and screws with shapes and sizes designed for internal fixation of facial fractures and reconstruction procedures. System implants are manufactured from either titanium or titanium alloy and are intended for single use only.

The Facial Plating System plates that are the subject of this 510(k) submission include variations of straight, angle, curved, L-shape, T-shape, double T-shape, Z-shape, X-shape, Y-shape, double Y-shape, H-shape, triangle, square, rectangle, matrix, mesh, orbital floor, LeFort, and chin options with various lengths and thickness. Plates are offered flat or pre-bent. Surgeons use cutting and bending instruments intraoperatively to contour flat plates to patient anatomy; pre-bent plates are contoured by Biomet Microfixation per surgeon specifications or patient anatomy as a convenience. The Facial Plating System screws range in diameters of 1.0mm to 2.3mm and lengths from 2.0mm to 29.0mm.

Sterility Information:
The plates and screws will be marketed as non-sterile, single-use devices.

Technological Characteristics:
The subject Facial Plating System devices are similar to the predicate devices in terms of indications, use, and design. The non-clinical testing data shown below demonstrate that the subject devices have equivalent or better mechanical performance when compared to the predicate devices. Minor differences in device geometry do not raise new issues of safety and efficacy.

Clinical Testing:
Clinical testing was not performed to support this submission.

Non-Clinical Testing:
Mechanical testing was performed to compare the subject devices to the predicate devices to measure:

- Failure Force (lbf) in Bending of Plates
- Rate of Deflection (in/lb) of Plates
- Push-Through Strength (lbs) of Plates
- Insertion Torque (in-oz) of Screws
- Fracture Torque (in-oz) of Screws

K121589

The non-clinical test results demonstrate that the mechanical performance of the subject Facial Plating System plates and screws are equivalent or better than the predicate devices and support the substantial equivalence to the predicate devices.

Substantial Equivalence:
Biomet Microfixation considers the Facial Plating System modifications equivalent to the Biomet Microfixation's (formerly Walter Lorenz Surgical's) Lorenz 1.0mm, 1.5mm, 2.0mm Plating System cleared under K953385, Paulus Titanium Mini Bone Plates and Bone Screws cleared under K862534, Wuertzburg Plates and Screws cleared under K854886, Lorenz Self-Drilling Screw cleared under K013954, and Lorenz 1.0mm System cleared under K922741.

In conclusion, the subject Biomet Microfixation Facial Plating System devices have the same intended use and similar technological characteristics to the legally marketed predicate devices. Non-clinical testing demonstrates that slight geometrical differences in the devices do not affect safety or effectiveness. The information presented supports substantial equivalence of the subject devices to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

SEP 21 2012

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

Re: K121589
Trade/Device Name: Biomet Microfixation Facial Plating System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: August 23, 2012
Received: August 24, 2012

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121589

Device Name: Biomet Microfixation Facial Plating System

Indications For Use:

These devices are implantable bone plates and bone screws for facial procedures including:

1. Fractures
2. Osteotomies
3. Reconstructive procedures
4. Revision procedures where other treatments or devices have failed

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)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices
510(k) Number: K121589