K081067

BIOMET MICROFIXATION, INC.

MAY - 9 2008

**510(k) Summary**

**Contact:** Biomet Microfixation
1520 Tradeport Drive
Jacksonville, FL 32218-2480
Kim Reed, Regulatory Affairs Manager
904-741-9443 fax 904-741-3912

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|---|---|---|---|
| **Common or Usual Name:** | Bone Plate | **Classification Name** | Plate, Fixation, Bone |
| **Device Classification:** | Class II | **Device Product Code:** | 76 JEY (21 CFR 872.4760) |

**Device Name:** Reconstruction / Fracture Plating System (TraumaOne)

**Intended Use:** The Titanium Fracture / Reconstructive Devices (TraumaOne) are intended for use in the stabilization and fixation of mandibular fractures and mandibular reconstructive surgical procedures.

**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.
5. If used in mandibular resection cases, the mandibular reconstructive devices must be supported using a graft. If mandibular reconstructive devices are not supported by a graft, the devices can be expected to fracture, bend, break or fail.

**Description:** The Mandibular Fracture / Reconstructive Devices (TraumaOne) are comprised of a variety of titanium fracture and reconstruction plates and screws with shapes and sizes designed for internal fixation of mandibular fractures and reconstruction procedures. The screws have locking and non-locking head features. The plates have threaded through holes (which allows them to work with either the locking or non-locking screws) and will include straight, angle, double angle, and crescent options with various lengths and thickness.

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

**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.
10. Mandibular devices can fracture, bend, break or fail if used to bridge a mandibular resection site, in the absence of a graft.

**Substantial Equivalence** Biomet Microfixation considers the Fracture / Reconstructive Devices (TraumaOne) equivalent to the Lorenz Titanium Fracture / Reconstructive Devices cleared under K001238 and Lorenz Reconstruction System cleared under K980512.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 9 2008

Ms. Kim Reed
Regulatory Affairs Manager
Biomet Microfixation
1520 Tradeport Drive
Jacksonville, Florida 32218

Re: K081067
Trade/Device Name: Mandibular Fracture/ Reconstruction Devices (TraumaOne)
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: March 14, 2008
Received: April 15, 2008

Dear Ms. Reed:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market,

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
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): K081067

Device Name: Mandibular Fracture / Reconstruction Devices (TraumaOne)

Indications For Use:

Intended for use in the stabilization and fixation of mandibular fractures and mandibular reconstructive surgical procedures.

Prescription Use [X] 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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices



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