BIOMET TRAUMA

NOV 19 2009

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.93.

Submitter:	EBI LLC d/b/a Biomet Trauma 100 Interpace Parkway Parsippany, NJ 07054
Establishment Registration Number:	2242816
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Contract Manufacturer/Sterilizer:	Biotech International 305, Allees de Craponne 13300 Salon de Provence, France Tel: (33)4 90 44 60 60 Fax: (33)4 90 44 60 61
Date Prepared:	November 17, 2009
Trade/Proprietary Name:	BioDrive Micro Screw System
Common/Usual Name:	Bone screw, Bone plate
Classification Name:	Plate, Fixation, Bone 888.3030 Screw, Fixation, Bone 888.3040
Device Panel/Product Code:	Orthopedics HRS and HWC

Device Description:
The Biomet BioDrive Micro Screw System consists of screws, a micro nail plate and ancillary instruments intended for surgery to aid in alignment and stabilization of fractures of small bones such as those in the foot, elbow, ankle, and hand.

Indications for Use:
The Biomet BioDrive Screw System is indicated for alignment and stabilization of small bone fractures.

Specifically:

- Fixation of small bones, such as those in the foot, ankle, wrist, elbow and hand for treatment of fractures, non-unions, or mal-unions
- Ligament reconstruction
- Osteochondritis dissecans
- Arthrodesis of the foot, ankle, wrist, elbow and hand
- Small bone osteotomies, including first metatarsal head osteotomy, metatarsal osteotomies, phalangeal osteotomies, and carpal/metacarpal osteotomies

These procedures may be indicated as a result of trauma, deformity, osteoarthritis, and rheumatoid arthritis.

Summary of Technology:
The technological characteristics (material, design, and sizing) of the implants and instruments comprising the BioDrive Micro Screw System are the same as or similar to the predicate devices.

Substantial Equivalence:
The Biomet BioDrive bone screw system is substantially equivalent to its predicate devices with respect to intended use and indications, technological characteristics, and principles of operation and do not present any new issues of safety or effectiveness. Examples of predicates include the Omnitech System distributed by TriMed Inc (K050681), the Self Countersinking Bone Screw distributed by Biomet (K013534) and the DynaFix Compression Bone Screw distributed by Biomet Trauma (K030706).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

EBI LLC D/B/A Biomet Trauma
% Ms. Shikha Gola
100 Interpace Parkway
Parsippany, New Jersey 07054

NOV 19 2009

Re: K092670
Trade/Device Name: BioDrive Micro Screw System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS, HWC
Dated: August 28, 2009
Received: August 31, 2009

Dear Ms. Gola:

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 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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: BioDrive Micro Screw System

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Prescription Use X (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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Janita J. for MXN

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092670