K091858

BIOMET® MICROFIXATION

510(k) Summary

JUL 22 2009

Contact: Biomet Microfixation
1520 Tradeport Drive
Jacksonville, FL 32218-2480
Kim Reed, Regulatory Affairs Manager
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Common or Usual Name: Bone Plate
Classification Name Single/multiple component metallic bone fixation appliances and accessories
Device Classification: Class II
Device Product Code: 87HRS (CFR 888.3030)

Device Name: Adkins Strut

Intended Use: This device is intended for use in surgical procedures to repair Pectus Excavatum and other chest wall deformities.

Contraindications:
1. Patients with mental or neurological conditions who are unwilling or incapable of following instructions.
2. Patients presenting metal sensitivity reactions.
3. Patients with insufficient quantity or quality of bone or fibrous tissue to allow remodeling.
4. Infection
5. The device should not be used to perform the minimally invasive repair of pectus exavatum (MIRPE or Nuss procedure), or used in conjunction with items typically used to perform the MIRPE surgery.

Description: The Biomet Microfixation Adkins Strut is a surgical implant intended to aid treatment of Pectus Excavatum and other sternal deformities. The strut provides the surgeon with a means to reposition bony structures (sternum, breastbone) by providing internal stabilization and fixation of the chest wall following surgical procedures such as the Ravitch procedure. The struts are available in various lengths with two holes on each end for sutures to secure the bar to the lateral chest wall. The titanium struts are used when the patient has a nickel allergy.

Sterility Information: The Adkins Struts will be marketed as non-sterile, single use devices.

Possible risks:
1. Metal sensitivity reactions or allergic reaction to the implant material.
2. Pain, discomfort, or abnormal sensation due to the presence of the device.
3. Surgical trauma; permanent or temporary nerve damage, permanent or temporary damage to heart, lungs, and other organs, body structures or tissues.
4. Skin irritation, infection, and pneumothorax.
5. Fracture, breakage, migration, or loosening of the implant.
6. Inadequate or incomplete remodeling of the deformity or return of deformity, prior to or after removal of implant.
7. Permanent injury or death.

Substantial Equivalence Biomet Microfixation considers the Adkins Struts equivalent to the American V. Mueller Adkins Strut (Pre-amendment device).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Biomet Microfixation, Inc.
% Ms. Kim Reed
Regulatory Affairs Manager
1520 Tradeport Drive
Jacksonville, Florida 32218-2480

JUL 22 2009

Re: K091058
Trade/Device Name: Adkins Strut
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: June 17, 2009
Received: June 19, 2009

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 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 (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Barbara Buehrup for

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): K091058

Device Name: Adkins Struts

Indications For Use:

This device is intended for use in surgical procedures to repair Pectus Excavatum and other chest wall deformities.

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)

Jeanette C. Jo

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

510(k) Number K091058