APR 16 2010

BIOMET TRAUMA

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: Biomet Trauma
100 Interpace Parkway
Parsippany, NJ 07054

Establishment Registration Number: 2242816

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Date Prepared: April 15, 2010

Trade/Proprietary Name: Peanut™ Growth Control Plating System

Common/Usual Name: Plates/Screws

Classification Name: Single/multiple metallic bone fixation appliances and accessories (21 CFR 888.3030)

Device Panel/Product Code: Orthopedics HRS/HWC

Device Description:
The Peanut™ Growth Control Plating System consists of two plate designs (arched and stepped) and solid and cannulated screws.

Indications for Use:

The Peanut™ Growth Control Plating System is designed for redirecting the angle of growth of long bone(s) in pediatric patients (patients who have not had physeal closure/reached skeletal maturity). This is useful for gradually correcting angular deformities in pediatric

patients with an open physis. Specific conditions/diseases for which the device will be indicated include valgus, varus, or flexion extension deformities of the knee (femur and/or tibia); valgus, varus or plantar flexion deformities of the ankle, valgus or varus deformities of the elbow, as well as radial or ulnar deviation, flexion or extension deformities of the wrist (radius).

Purpose of Submission
The purpose of this submission is to:

- Add 16mm screw lengths
- Add a contraindication to the previously cleared labeling for the Peanut™ Growth Control Plating System
- Allow the implants of the Peanut™ system to be sold in a non-sterile configuration either packaged individually or in a kit/tray packaging configuration.

The contraindications for the Peanut™ Growth Control Plating System are:

1. Physeal closure/skeletal maturity
2. Active Infection
3. Patient conditions including blood supply limitations, and insufficient quantity or quality of bone.
4. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions or materials.
5. Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation of the device.

The first contraindication is being added to the labeling to limit the use of the device to the intended population.

Summary of Technologies:
The technological characteristics of the Peanut™ Growth Control Plating System are the same, or similar to, other legally marketed predicate devices. The Orthofix eight-Plate device is distributed in a non-sterile configuration, and has a similar contraindication in its 510(k) summary.

Substantial Equivalence:
The modifications to the Peanut™ Growth Control Plating System do not raise any issues of safety or effectiveness. The modified product is equivalent to the Growth Control Plating System released in premarket notification K070823, and to the Orthofix eight-Plate previously released under K031493. Pull-out strength testing was provided to support substantial equivalence.

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

Biomet Trauma (aka EBI LP)
% Margaret F. Crowe
100 Interpace Pkwy.
Parsippany, New Jersey 07054

APR 16 2010

Re: K093880
Trade/Device Name: Peanut Growth Control Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: April 15, 2010
Received: April 16, 2010

Dear Ms. Crowe:

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,

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): K093880 (pg 1/1)

Device Name: Peanut™ Growth Control Plating System

The Peanut™ Growth Control Plating System is designed for redirecting the angle of growth of long bone(s) in pediatric patients (patients who have not had physeal closure/reached skeletal maturity). This is useful for gradually correcting angular deformities in pediatric patients with an open physis. Specific conditions/diseases for which the device will be indicated include valgus, varus, or flexion extension deformities of the knee (femur and/or tibia); valgus, varus or plantar flexion deformities of the ankle, valgus or varus deformities of the elbow, as well as radial or ulnar deviation, flexion or extension deformities of the wrist (radius).

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)

Temperature

Barbara Brenner

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

510(k) Number K093880