K111176

AUG 15 2011

510(k) Summary

Submitter Information:

OsteoMed L. P.
3885 Arapaho Road
Addison, Texas 75001
Phone: (972) 677-4600
Fax: (972) 677-4601

Contact Person: Piedad Peña

Date Prepared: July 27, 2011

Device Information:

Proprietary/Trade Name: OsteoMed Low Profile Neuro Fixation System
Common Name: Low Profile Neuro Plates

Classification Name:

- Regulation Number: 21 CFR 882.5320
- Regulation Name: Preform alterable cranioplasty plate
- Product Code:
  - GWO, Plate, cranioplasty, preformed, alterable
  - GXR, Burr hole cover

Device Class: 2
510(k): K111176

Predicate Devices:

OsteoMed SBF system, K911936
Classification Name: Intraosseous fixation screw or wire (21CFR 872.4880, Product Code DZL)
Device Class: 2

OsteoMed M3 SBF system (Addendum), K924138
Classification Name: Bone Plate (21CFR 872.4760, Product Code JEY)
Device Class: 2

Device Description:

The ***OSTEOMED Low Profile Neuro Fixation System*** is comprised of plates, screws and instrumentation. The system features plates ranging from 0.25mm to 1.0mm thick, 1.2 mm to 1.6mm diameter standard screws in lengths from 2.0mm to 8.0mm and Auto-Drive screws in 1.2mm to 1.6mm diameters in lengths from 3.0mm to 8.0mm.

The instruments include drill bits, plate bending forceps, plate holding forceps, plate cutters, cannulae, taps, countersinks and screwdrivers to facilitate the placement of screws and modification of plates.

The screws are made from Titanium Alloy (ASTM F-136). The plates are made from Titanium Alloy (ASTM F-136) or commercially pure Titanium (ASTM F-67). The instrumentation is made from various grades of surgical grade stainless steel, anodized aluminum, and/or medical grade plastic.

Intended Use:

The OsteoMed Low Profile Neuro Fixation System is indicated for use in osteotomies, fractures or reconstruction of the cranial bones. The implants and drills are single use only.

Technological Characteristics:

The basis of substantial equivalence for the modification of the OsteoMed SBF system, K911936, is based on the similarities in design, material, function, performance, sterilization, and intended as the predicate device.

Performance / Clinical Data:

The low profile neuro plates performed equivalent or with greater strength than the existing neuro predicate devices based on verification testing. Verification consisted of mechanical testing and finite element analysis comparisons against the predicate neuro plates. Limulus Amebocyte Lysate (LAL) testing was conducted in accordance to ANSI/AAMI ST72:2002.

Materials used for the device are the same as the predicate device with changes from CP Ti to Ti-Alloy to maintain equivalent or greater strength to the predicate devices. These materials are biocompatible and already part of the predicate neuro devices.

Clinical Testing was not required for this modification to support substantial equivalence.

Conclusion:

The basis of substantial equivalence for the addition of the low profile neuro plates to the current neuro plates of the OsteoMed SBF system, K911936, is based on the similarities in design, material, function, sterilization, and intended use to the predicate device. OsteoMed believes that the modifications do not raise any new safety or effectiveness issues.

OsteoMed L.P.
3885 Arapaho Road
Addison, Texas 75001
(972) 677-4600 FAX: (972) 677-4601
Customer Service: (800) 456-7779

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

Osteomed L.P.
Mr. Piedad Pena
Senior Regulatory Specialist
3885 Arapaho Road
Addison, Texas 75001

AUG 15 2011

Re: K111176
Trade/Device Name: OsteoMed Low Profile Neuro Fixation System
Regulation Number: 21 CFR 882.5320
Regulation Name: Preformed Alterable Cranioplasty Plate
Regulatory Class: II
Product Code: GWO, GXR
Dated: July 27, 2011
Received: July 28, 2011

Dear Mr. Pena:

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,

for

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): K111176

Device Name: OSTEOMED Low Profile Neuro Fixation System

Indications for Use:

The OSTEOMED Low Profile Neuro Fixation System is indicated for use in osteotomies, fractures or reconstructions of the cranial bones.

Implants and drills are single use only.

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)

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

510(k) Number: K111176