K121304

510(k) Summary

AUG 22 2012

Submitter Information:

OsteoMed
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Contact Person: Mrs. Piedad Peña

Date Prepared: August 20, 2012

Device Information:

Proprietary/Trade Name: OsteoMed Cranial Distraction System
Common Name: Cranial Distraction System

Classification Name:

- Regulation Number: 21 CFR 882.5330
- Regulation Name: Preformed nonalterable cranioplasty plate
- Product Code:
  - PBJ

Device Class: II

Predicate Devices:

KLS-Martin, K003883
Classification Name: Bone Plate (21CFR 872.4760, Product Code JEY)
Device Class: II

Device Description:

The OsteoMed Cranial Distraction System is comprised of distractors, spacers, screws and instrumentation. The distractor is an internal distraction device for bone elongation of cranial bones. The distractor is anchored between the osteotomy with 1.2mm standard or 1.2mm AutoDrive screws previously cleared under K924138 and K023260, respectively. The distractor is activated using a distractor tool via the distraction rod. The distraction rod is preassembled within the distractor device. The non-threaded portion of the distractor rod can be removed during the consolidation period. The distractors, spacers, and screws are removed after consolidation.

The instruments include distractor tool, drills, plate bending forceps, holding forceps, plate cutters and screwdrivers to facilitate the placement of screws and modification of the distractor assembly plates. A distractor rod removal tool is also available to partially remove the distractor rod leaving the distracted device in place.

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

Intended Use:

The ***OSTEOMED Cranial Distraction System*** intended for use in the treatment of cranial conditions such as syndromic craniosynostosis and congenital deficiencies in which osteotomies and gradual bone distraction are indicated. This device is intended to provide temporary stabilization and gradual lengthening of the cranial bones. This device is intended to be removed after consolidation. The ***OSTEOMED Cranial Distraction System*** is intended for single patient use only.

Intended use is equivalent to the KLS and OsteoMed predicate devices.

Technological Characteristics:

The KLS predicate device is an internal distractor for bone elongation, which distracts via a threaded rod. OsteoMed internal distractor also uses a threaded rod for distraction and is anchored using bone screws. Both use a distraction tool for distraction.

Materials used for the distractor are the same as the predicate devices, Titanium/Titanium Alloy. These materials are biocompatible.

Performance / Clinical Data:

The ***OSTEOMED Cranial Distraction System*** performed equivalent as the KLS predicate device based on verification testing. Verification testing consisted of mechanical testing and comparisons against the KLS predicate device. The intended use if the device is the same as the KLS Predicate Device.

Clinical Testing is not required to support substantial equivalence.

In conclusion, the device is safe and effective and performs as well as the predicate device.

Substantial Equivalence:

The basis of substantial equivalence for this device is based on similarities in intended use, material, function, performance, sterilization design, technology and operational principle to the predicate device, KLS-Martin (K003883) Distraction System, based on their promotional materials, labeling and clearance letter.

Due to the similarity of materials and design to the predicate device, OsteoMed believes that the OsteoMed Cranial Distraction System does not raise any new safety or effectiveness issues.

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Public Health Service

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OsteoMed
c/o Mrs. Piedad Peña
Sr. Regulatory Affairs Specialist
3885 Arapaho Road
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AUG 2 2 2012

Re: K121304
OsteoMed Cranial Distraction System
Regulation Number: 21 CFR 885.5330
Regulation Name: Preformed nonalterable cranioplasty plate
Regulatory Class: Class II
Product Code: PBJ
Dated: July 29, 2012
Received: July 31, 2012

Dear Mrs. Peña:

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,

Kesia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K121304

Indications for Use

510(k) Number (if known): K121304

Device Name: OsteoMed Cranial Distraction System

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The OsteoMed Cranial Distraction System implants are intended for 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 Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K121304