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OSTEOMED CORPORATION

510(k) Summary

Device Proprietary Name:	OsteoMed Cranial Flap Fixation System
Device Common Name:	Intraoral Distractor
Classification Name:	GXN, Plate, Cranioplasty, Preformed, Non-Alterable
Name of Submitter:	OsteoMed Corporation 3750 Realty Road Addison, Texas 75001 Phone: (972) 241-3401 Fax: (972) 241-3507
Contact Person:	Dawn T. Holdeman
Date Prepared:	July 12, 2001

Summary:

This submission describes the OsteoMed Cranial Flap Fixation System intended for the re-attachment of the bone flap after a craniotomy. The OsteoMed Cranial Flap Fixation System is intended for single patient use only.

The OsteoMed Cranial Flap Fixation System is a clamping device which has a threaded post attached to an inferior disk and a threading superior disk that threads down the post to secure a sandwich fit of the Cranial Flap and cranium between the inferior and superior plate. The device locks into place once the desired fixation is achieved by the surgeon. The OsteoMed Cranial Flap Fixation devices are available in a range of 10mm to 22mm disk diameters.

Equivalence for this device is based on similarities in intended use, material, design and operational principle to the MacroPore CraniLoc (K002334), Aesculap Craniofix Titanium Clamp System (K972332) and the Lorenz Rapidflap Cranial Clamp (K991029).

Due to the similarity of materials and design to both pre-enactment and post-enactment devices, OsteoMed believes that the OsteoMed Cranial Flap Fixation System does not raise any new safety or effectiveness issues.

3750 Realty Road
Addison, Texas 75001-4311
(972) 241-3401 FAX: (972) 241-3507
Customer Service: (800) 456-7779

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 01 2003

Ms. Dawn T. Holdeman
Regulatory Affairs and Document Control
Osteomed Corp.
3885 Arapaho Road
Addison, TX 75001

Re: K022277
Trade/Device Name: Cranial Flap Fixation System
Regulation Number: 21 CFR 882.5330
Regulation Name: Preformed nonalterable cranioplasty plate
Regulatory Class: II
Product Code: GXN
Dated: January 9, 2003
Received: January 10, 2003

Dear Ms. Holdeman:

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.

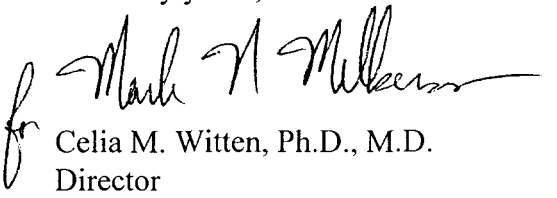
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4679. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html .

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

OsteoMed "Indications for Use" Submission

510(k) Number: K022277

Device Name:	Osteomed Cranial Flap Fixation System
Indication for Use:	Intended for the re-attachment of the bone flap after a craniotomy. The OsteoMed Cranial Flap Fixation System is intended for single patient use only.

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022277