



JUN - 2 2006

## 510(k) Summary

Device Proprietary Name: OsteoMed 1<sup>st</sup> MPJ Hemi Implant System

Device Common Name: Hemi Toe Implant

Classification Name: KWD  
Prosthesis, Toe, Hemi, Phalangeal

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

Contact Person: Dawn D. Tindall

Date Prepared: May 9, 2006

### Summary:

The OsteoMed 1<sup>st</sup> MPJ Hemi Implant is a one piece implant to supplement first metatarsal phalangeal joint arthroplasty. The implant is designed to replace the distal base of the proximal phalanx and provide a smooth articular surface for the adjacent first metatarsal head. It is available in several sizes in direct per portion to the anatomic construct of the distal base of the proximal phalanx. Primary fixation is intended via a press fit bone implant interface. The OsteoMed 1<sup>st</sup> MPJ Hemi Implant is made of cobalt chromium (ASTM F-799) and may also be provided with a titanium plasma coated stem.

The OsteoMed 1<sup>st</sup> MPJ Hemi Implant System is indicated for use in the treatment of patients with inflammatory arthritis in the first metatarsal joint in the presence of good bone stock and integrity of the first metatarsal head, along with the following clinical conditions; hallux valgus, hallux rigidus, and an unstable or painful metatarsophlangeal joint. OsteoMed 1<sup>st</sup> MPJ Hemi Implants are intended for single use only.

Equivalence for this device is based on similarities in intended use, material, design and operational principle to the BioPro Hemi MP Joint (K041595), the Kinetikos Medical, K2 Hemi Toe Implant System (K023770) and the Futura BioMedical Metal Hemi Toe Implant (K971047).

Due to the similarity of materials and design to the predicate devices, OsteoMed believes that the OsteoMed 1<sup>st</sup> MPJ Hemi Implant System does not raise any new safety or effectiveness issues.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Ms. Dawn D. Tindall  
Regulatory Affairs  
OsteoMed L.P.  
3885 Arapaho Road  
Addison, Texas 75001

Re: K060536  
Trade/Device Name: 1<sup>st</sup> MPJ Hemi Implant  
Regulation Number: 21 CFR 888.3730  
Regulation Name: Toe joint phalangeal (hemi-toe) polymer prosthesis  
Regulatory Class: Class II  
Product Code: KWD  
Dated: May 10, 2006  
Received: May 11, 2006

Dear Ms. Tindall:

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.

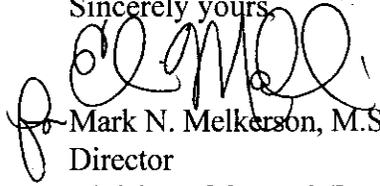
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is written in a cursive style with a large initial "M".

Mark N. Melkerson, M.S.

Director

Division of General, Restorative and  
Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K060536

Device Name: OsteoMed 1<sup>st</sup> MPJ Hemi Implant System

### Indications for Use:

Indicated for use in the treatment of patients with inflammatory arthritis in the first metatarsal joint in the presence of good bone stock and integrity of the first metatarsal head, along with the following clinical conditions: hallux valgus, hallux rigidus and an unstable or painful metatarsophalangeal joint. OsteoMed 1<sup>st</sup> MPJ Hemi 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 General, Restorative,  
and Neurological Devices**

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(Posted November 13, 2003)

**510(k) Number** K060536