SEP 16 2004

K042072

## 510(k) Summary

**General Information**

**Manufacturer:**

Skeletal Kinetics, LLC
10201 Bubb Road
Cupertino, CA 95014

**Establishment Registration Number:** 3003890476

**Contact Person:**

Duran Yetkinler, M.D., Ph.D
Vice President Regulatory Affairs, and
Research and Design

**Date Prepared:** July 29, 2004

**Device Description**

**Classification Name:**

Class II:84 GXP (21 CFR 882.5300) Methyl Methacrylate for Cranioplasty; 79 FWP (878.3550) Prosthesis, Chin, Internal
Panel: Neurosurgery

**Trade Name:**

Callos™ CMF Bone Void Filler (subject to change)

**Generic/Common Name:** Hydroxyapatite Cement

**Predicate Devices**

- Callos Bone Void Filler K030554
- BoneSource HAC (Hydroxyapatite Cement) K032366
- Synthes Fast Set Putty (Norian CRS) K012589

**Intended Use**

Callos CMF Bone Void Filler is a calcium phosphate bone void filler indicated for the repair or filling of neurosurgical burr holes, other craniofacial defects and craniotomy cuts with a surface area no larger than 25cm$^2$. Callos CMF Bone Void Filler may be used in the restoration or augmentation of bony contours of the craniofacial skeleton, including fronto-orbital, malar, and mental areas.

**Product Description**

Callos CMF Bone Void Filler is an impactable and moldable single use, biocompatible calcium phosphate bone void filler, that remodels and is replaced by bone during the healing process. Callos CMF is packaged in various kit sizes (3cc, 5cc, and 10cc).

**Substantial Equivalence**

The subject and predicate devices are all classified as Methyl Methacrylate for Cranioplasty, and are intended for use in a variety of craniomaxillofacial applications. In

establishing substantial equivalence to the predicate devices, Skeletal Kinetics, LLC evaluated the indications for use, materials, technology, and product specifications. Completed performance testing and device comparison demonstrated that the subject device is substantially equivalent to the predicate devices, and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 16 2004

Duran Yetkinler, M.D., Ph.D.
Vice President, Regulatory Affairs, and Research and Design
Skeletal Kinetics
10201 Bubb Road
Cupertino, California 95014

Re: K042072
Trade Name: Callos™ CMF Bone Void Filler
Regulation Number: 21 CFR 882.5300
Regulation Name: Methyl methacrylate for cranioplasty
Regulatory Class: II
Product Code: GXP
Dated: July 29, 2004
Received: August 06, 2004

Dear Dr. Yetkinler:

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) 594-4659. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

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

## Indications Statement

Device Name: Callos™ CMF Bone Void Filler
510(k) Number: K042072

Indications for use:

Callos CMF Bone Void Filler is a calcium phosphate bone void filler indicated for the repair or filling of neurosurgical burr holes, other craniofacial defects and craniotomy cuts with a surface area no larger than 25cm$^2$. Callos CMF Bone Void Filler may be used in the restoration or augmentation of bony contours of the craniofacial skeleton, including fronto-orbital, malar, and mental areas.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k)_____

Prescription Use (Per 21 CFR 801.109) X OR Over-the-Counter Use ____

Miriam C. Provost

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

**510(k) Number** K042072