K051784

JUL 20 2005

510(k) Summary

Skeletal Kinetics, LLC
OsteoVation™ CMF Bone Void Filler

General Information

Submitters Name/Address:	Skeletal Kinetics 10201 Bubb Road Cupertino, CA 95014
Establishment Registration Number:	3003890476
Contact Person:	Duran Yetkinler Vice President, Product Development and Regulatory Affairs
Phone Number:	(408) 366.5002
Date Prepared:	June 30, 2005

Device Description

Trade Name:	OsteoVation CMF Bone Void Filler
Generic/Common Name:	Hydroxyapatite Cement
Classification Name:	84 GXP

Predicate Devices

Callos Bone Void Filler	K051123; cleared on June 3, 2005
Callos CMF Bone Void Filler	K042072; cleared on Sept. 16, 2004

Product Description

OsteoVation is a calcium phosphate bone void filler which can either be injected or digitally impacted into the targeted void. It is a single use only proudct.

Intended Use

OsteoVation 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 $25cm^2$. OsteoVation CMF Bone Void Filler may be used in the restoration or augmentation of bony contours of the craniofacial skeletaon, including fronto-orbital, malar, and mental areas.

Substantial Equivalence

This Special 510(k) proposes a modification in materials for OsteoVation, which was previously cleared under K042072 on June 3, 2005. The indications for use, technology, principle of operation, packaging, and sterilization parameters of OsteoVation remain the same as in the predicate cleared 510(k)s.

Summary of Safety and Effectiveness

OsteoVation, as described in this submission, is substantially equivalent to the predicate, unmodified Callos CMF. The proposed modification in materials, is not a substantial change or modification, and does not significantly affect the safety or efficacy of OsteoVation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 20 2005

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

Re: K051784
Trade/Device Name: OsteoVation™ CMF Bone Void Filler
Regulation Number: 21 CFR 882.5300
Regulation Name: Methyl methacrylate for cranioplasty
Regulatory Class: II
Product Code: FWP, GXP
Dated: June 30, 2005
Received: July 1, 2005

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

Sincerely yours,

for Miriam C. Provost, Ph.D
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known)

Device Name: OsteoVation™ CMF Bone Void Filler

Indications for use:

OsteoVation 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 $25cm^2$. OsteoVation CMF Bone Void Filler may be used in the restoration or augmentation of bony contours of the craniofacial skeletaon, 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)

Prescription Use X AND/OR Over-the-Counter Use
(Per 21 CFR 801.109) (21 CFR 801 Subpart C)

Division of General, Restorative
and Neurological Devices

510(k) Number K051784