K030554

MAY 2 0 2003

510(k) Summary

Sponsor:	Skeletal Kinetics, LLC 10201 Bubb Road, Cupertino, CA 95014
Contact Person:	Duran Yetkinler, M.D., Ph.D.
Phone Number:	408 366 5002
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Prepared:	February 18, 2003
Trade Name:	Callos™
Common Name:	Bone Graft Substitute
Classification:	Unclassified
Product Code:	87 MVQ

Predicate Device: Callos Bone Void Filler is substantially equivalent to Norian SRS Bone Void Filler (K011897).

Device Description: Callos Bone Void Filler is an injectable, moldable and biocompatible bone void filler. Callos Bone Void Filler resorbs and is replaced with bone during the healing process. The 3 cc, 5 cc, and 10 cc Callos Bone Void Filler kits are provided sterile and are for single use only.

Intended Use/Indications for Use: Callos Bone Void Filler is indicated to fill bony voids or gaps of the skeletal system (i.e. extremities, spine, and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Callos Bone Void Filler is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. The product provides a bone void filler that resorbs and is replaced by bone during the healing process.

Technological Characteristics: Similar to the predicate device, Callos Bone Void Filler is an injectable, moldable, biocompatible, resorbable calcium phosphate based material intended for identical indications.

Performance Data: Non-clinical testing included material properties such as density, porosity, dimensional stability, injectability, setting time, working time, pH, and setting temperature. Biocompatibility testing demonstrated that the material is non-cytotoxic, non-systemic toxic, non-mutagenic, non-irritative, non-pyrogenic, and non-sensitizing. Comparative testing with the predicate device showed equivalence in terms of solubility and dissolution rate, X-Ray Diffraction (XRD), Fourier Transform Infrared (FTIR) spectroscopy and elemental analysis. Animal testing demonstrated substantial equivalence to the predicate device following *in vivo* implantation. Histological, chemical, crystallographical, and mechanical analyses showed substantial equivalence.

Basis for Substantial Equivalence: The Callos Bone Void Filler has the same intended use, identical indications, and very similar technological characteristics as the predicate device. Any minor technological differences between Callos Bone Void Filler and its predicate device do not raise any new issues of safety or effectiveness.

Functional, biocompatibility, and animal testing results show that the Callos Bone Void Filler is as safe and effective as the predicate device. Thus, the Callos Bone Void Filler is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 0 2003

Skeletal Kinetics, LLC
c/o Mr. Howard Holstein
Regulatory Counsel
Hogan & Hartson, LLC
555 13th Street, N.W.
Washington, DC 20004

Re: K030554
Trade/Device Name: Callos™ Bone Void Filler
Regulatory Class: Unclassified
Product Code: MQV
Dated: February 20, 2003
Received: February 21, 2003

Dear Mr. Holstein:

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,

Mark N. Melkerson

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

510(k) Indications for Use

510(k) Number (if known): K030554

Device Name: Callos Bone Void Filler

Indications for use:

Callos Bone Void Filler is indicated to fill bony voids or gaps of the skeletal system (i.e. extremities, spine, pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Callos Bone Void Filler is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. The product provides a bone void filler that resorbs and is replaced by bone during the healing process.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(per 21 CFR 801.109)

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

510(k) Number K030554