K100986

Skeletal Kinetics

A COLSON ASSOCIATE

JUL 20 2010

510(k) Summary

General Information as required by 21 CFR 807.92 (a) (1)

Submitters Name/address:	Skeletal Kinetics® LLC 10201 Bubb Road Cupertino, CA 95014, USA
Contact Person:	Christine Kuo, Director, Regulatory Affairs and Quality Assurance
Contact Numbers:	Phone: (408) 350-5842, Fax: (408) 366-1077
Date Prepared:	June 25, 2010

Device Name as required by 21 CFR 807.92 (a) (2)

Trade Names:	Callos® Bone Void Filler (Callos), SKaffold™ Next Generation Bone Void Filler, OsteoVation® EX Bone Void Filler
Common Name:	Resorbable Calcium Salt Bone Void Filler
Classification:	21 CFR 888.3045
Product Code:	MQV

Predicate Devices as required by 21 CFR 807.92 (a) (3)

The subject device is substantially equivalent in safety and effectiveness to the following legally marketed devices (predicates):

I. MasterGraft® Resorbable Ceramic Granules of Medtronic (K082918)
II. MasterGraft® Resorbable Ceramic Granules of Medtronic (K082917)
III. MBCP™ of Biomatlante (K051774)
IV. Callos® of Skeletal Kinetics (K030554 and K051123)

Device Description as required by 21 CFR 807.92 (a) (4)

Callos Bone Void Filler is a moldable and biocompatible calcium phosphate bone void filler. The single-use Callos Kit contains the necessary components for mixing of the bone void filler. The Callos sterile kit contains: Calcium Phosphate Powder, Dilute Sodium Silicate Liquid, and a Mixing System (Mixing Bowl, Pestle and Spatula).

Intended Use as required by 21 CFR 807.92 (a) (5)

Callos is indicated to fill bony voids or gaps of the skeletal system (i.e. extremities, pelvis) not intrinsic to the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Callos can be used with autograft as a bone graft extender. Callos resorbs and is replaced by bone during the healing process.

Summary of Technological Characteristics as required by 21 CFR 807.92 (a) (6)

Callos is comprised of two working components: a calcium phosphate powder and a sodium silicate solution. The basic design of Callos requires the end-user to mix the powder component with the liquid solution to create a paste-like substance to be used as a bone graft extender. The device resorbs and is replaced by bone during the healing process.

Summary of Non-clinical Tests as required by 21 CFR 807.92 (b) (1)

The biocompatibility of Callos is in accordance with the standard set forth in ISO 10993-1, *Biological Evaluation of Medical Devices* and the radiation sterilization validation of Callos is compliant to ANSI/AAMI/ISO 11137-2:2006, *Sterilization of Health Care Products - Radiation - Establishing the Sterilization Dose*. These tests were evaluated during Callos® K030554 and K051123 clearances.

Callos is a previously cleared and commercially marketed calcium phosphate bone void filler. The physical/mechanical characteristics of Callos cement with added morselized bone was evaluated using setting test (modified ASTM test method) and X-ray Diffraction (XRD) phase analysis and compared with predicate device.

Summary of Clinical Tests as required by 21 CFR 807.92 (b) (2)

Callos, an orthopedic bone void filler, is composed of calcium phosphate salts (tri-calcium phosphate) that when mixed with a dilute sodium silicate solution form a thick paste. The resulting hardened material is composed of hydroxyapatite similar to the mineral phase of native bone tissue. There are no adverse metabolic breakdown products following implantation of hydroxyapatite, this material is the principal constituent of many approved orthopedic devices including Callos bone void filler.

The purpose of this 510(k) notification is to expand Callos' indications so that it may be used with autograft as a bone graft extender. The ewe study demonstrated that Callos could also be used as an orthopedic bone graft extender; Callos is substantially

equivalent to previously approved bone graft extenders predicate (I, II & III) and to bone void filler predicate (I, II, III, and IV) as described below:

Predicate device I (K082918), MasterGraft Resorbable Ceramic Granules of Medtronic is a bone void filler with a mixture of 60% hydroxyapatite and 40% β-tricalcium phosphate formulation (may also be provided in a 15% hydroxyapatite and 85% β-tricalcium phosphate formulation). Similar to Callos, it is a single use sterile osteoconductive implant and can be used with autograft as a bone graft extender.

Predicate device II (K082917), MasterGraft Resorbable Ceramic Granules of Medtronic is a bone void filler with a mixture of 60% hydroxyapatite and 40% β-tricalcium phosphate formulation (may also be provided in a 15% hydroxyapatite and 85% β-tricalcium phosphate formulation). Similar to Callos, it is a single use sterile osteoconductive implant to be used as a bone void filler or combined with autograft as bone graft extender to be use in maxillofacial region.

Predicate device III (K051774), MBCP of Biomatlante is a bone void filler with a mixture of 60% hydroxyapatite and 40% β-tricalcium phosphate. Similar to Callos, it is a single use sterile implant, and can be used with autograft as a bone graft extender.

Predicate device IV (K030554, K051123), Callos of Skeletal Kinetics, the same device as the subject device for this 510k notification, is a bone void filler as describe above.

Conclusion as required by 21 CFR 807.92 (3)

The summary above shows that Callos is substantially equivalent to the predicate devices and the tests demonstrate that the device is as safe, as effective, and performs as well as the legally market devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Skeletal Kinetics, LLC
% Ms. Christine Kuo
Director, Regulatory Affairs
& Quality Assurance
10201 Bubb Road
Cupertino, California 95014

JUL 20 2010

Re: K100986
Trade/Device Name: Callos® Bone Void Filler
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: June 3, 2010
Received: June 4, 2010

Dear Ms. Kuo:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: **Indications for Use**

510(K) Number (if Known): K100986

Device Name: Callos® Bone Void Filler

Indications for Use:

Callos Bone Void Filler is indicated to the following indications:

1. To fill bony voids or gaps of the skeletal system (i.e. extremities, spine, pelvis) not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.
2. To be used with autograft as a bone graft extender (i.e. extremities, and pelvis only).

Callos resorbs and is replaced by bone during the healing process.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100986