510(K) Summary

Date: August 10, 2007

Submitted by: Lisa Simpson
Regeneration Technologies, Inc.
11621 Research Circle
Alachua, FL 32615
Phone: 386-418-8888 Fax: 386-418-1627

Proprietary Name:
BioSet™ XCh

Common Name:
filler, bone void, osteoinduction (w/o human growth factor)

Product Code:
MBP, Orthopedics Panel

Code Section:
21 CFR 888.3045

Substantial Equivalence:
Data demonstrating substantial equivalence of BioSet™ XCh to predicate devices has been submitted.

Description:
BioSet™ XCh is a combination of bovine bone chips processed with the BioCleanse® Tissue Sterilization Process, human demineralized bone matrix, and a carrier derived from DBM from the same donor. BioSet™ XCh is available in volumes from 1 to 32cc.

Intended Use:
BioSet™ XCh is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. These products are indicated to be packed into bony voids or gaps of the skeletal system (e.g., the extremities, spine, ilium and/or pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

Summary of Technological Characteristics:
The DBM and bovine bone chips are processed in the same manner as the predicate BioSet™ XC. BioSet™ XCh is simply a substitution of human DBM-derived carrier for the porcine gelatin carrier in the BioSet™ XC product. The source of bovine bone used in BioSet™ XCh is a closed herd located in the U.S.A. Viral inactivation studies of the manufacturing process demonstrate a significant reduction of a representative panel of viruses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 25 2008

Regeneration Technologies, Incorporated
c/o Mr. Travis Arola
Regulatory Affairs Manager
11621 Research Circle
P.O. Box 2650
Alachua, FL 32616-2650

Re: K072238
Trade/Device Name: Bioset XCh
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV, MPB
Dated: December 21, 2007
Received: December 26, 2007

Dear Mr. Arola:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
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): K072238

Device Name:

BioSet™ XCh

Indications for Use:

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

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

510(k) Number K072238