Regeneration® TECHNOLOGIES, INC.

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510(K) Summary

K060180

SEP - 6 2006

Date: January 20, 2006

Submitted by: Lisa Simpson
Regeneration Technologies, Inc.
11621 Research Circle
Alachua, FL 32615
Phone: 386-418-8888 Fax: 386-462-3821

Proprietary Name:
BioSet™ XC

Common Name:
Filler, bone void, calcium compound

Classification:
MQV, Orthopedics Panel

Code Section:
21 CFR 888.3045

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

Description:
BioSet™ XC is a combination of bovine bone processed with the BioCleanse® Tissue Sterilization Process, human demineralized bone matrix, and porcine gelatin. BioSet™ XC is available in volumes from 1 to 32cc.

Intended Use:
BioSet™ XC 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:
BioSet™ XC is composed of bovine bone chips, human demineralized bone matrix (DBM) and porcine gelatin. The DBM and porcine gelatin are processed in the same manner as the predicate RTI Allograft Paste IC. The bovine bone is processed in the same manner as the predicate STERLING® Cancellous Chips. BioSet™ XC is simply a substitution of bovine bone chips for the human bone chips in the RTI Allograft Paste IC product. The source of bovine bone used in BioSet™ XC 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

Regeneration Technologies, Inc.
c/o Ms. Lisa Simpson
Director of Regulatory Affairs
11621 Research Circle
P.O. Box 2650
Alachua, FL 32615

SEP - 6 2006

Re: K060180
Trade/Device Name: BioSet™ XC
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV, MBP
Dated: July 14, 2006
Received: July 14, 2006

Dear Ms. Simpson:

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Buchup

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Devices Evaluation
Center for Devices and
Radiological Devices

Enclosure

Indications for Use

510(k) Number (if known): K060180

Device Name:

Indications for Use: BioSet™ XC 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.

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)

Barbara Bucchino for MKM

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

510(k) Number K060180