Regeneration™ TECHNOLOGIES, INC.

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AUG 15 2005

510(K) Summary

K051615
Date: August 5, 2005

Submitted by: Carrie Hartill
Regeneration Technologies, Inc.
11621 Research Circle
Alachua, FL 32615
Phone: 386-418-8888 x4382
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Proprietary Name:
STERLING® Cancellous Chips
STERLING® Cancellous Cubes

Common Name:
Filler, bone void, calcium compound

Classification:
MQV, Orthopedics Panel

Code Section:
21 CFR 888.3045

Substantial Equivalence:
STERLING® Cancellous Chips and STERLING® Cancellous Cubes are substantially equivalent to PolyGraft™ BGS in design and function, and are composed of bovine bone processed in the same manner as the STERLING® Interference Screw ST.

Description:
STERLING® Cancellous Chips and STERLING® Cancellous Cubes are manufactured from bovine bone processed with the BioCleanse® Tissue Sterilization Process. STERLING® Cancellous Chips and STERLING® Cancellous Cubes are provided in 1-10mm sizes, with 15-90cc per package.

Intended Use:
STERLING® Cancellous Chips and STERLING® Cancellous Cubes are indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure. They are indicated to be placed into bony voids or gaps of the skeletal system (e.g., 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 void filler that remodels into the recipient's skeletal system.

Summary of Technological Characteristics:
STERLING® Cancellous Chips, STERLING® Cancellous Cubes, and PolyGraft™ BGS have substantially equivalent design and function, but are composed of different materials. The STERLING® Cancellous Chips and STERLING® Cancellous Cubes are constructed of bovine bone processed in the same manner as the STERLING® Interference Screw ST. The source of bovine bone used in the manufacture of STERLING® Cancellous Chips and STERLING® Cancellous Cubes is a closed herd located in the U.S.A.

STERLING® Cancellous Chips and STERLING® Cancellous Cubes have been shown to remodel comparably to allograft in an animal model. A viral inactivation study using a worst-case representation of the BioCleanse® process, used in the manufacture of STERLING® Cancellous Chips and STERLING® Cancellous Cubes, has shown a greater than six log reduction of a panel of viruses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2005

Ms. Carrie Hartill
Regeneration Technologies, Inc.
11621 Research Circle
Alachua, Florida 32615

Re: K051615
Trade/Device Name: STERLING® Cancellous Chips
STERLING® Cancellous Cubes
Regulation Number: 21 CFR 888.3045
Regulation Name: Reabsorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: August 5, 2005
Received: August 8, 2005

Dear Ms. Hartill:

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/industry/support/index.html.

Sincerely yours,

Mark Melkerson
Acting 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): _____

Device Name: STERLING® Cancellous Chips
STERLING® Cancellous Cubes

Indications for Use: STERLING® Cancellous Chips and STERLING® Cancellous Cubes are indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure. They are indicated to be placed into bony voids or gaps of the skeletal system (e.g., 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 void filler that remodels into the recipient's skeletal system.

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

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

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ivision Sign-Off)
ivision of General, Restorative
nd Neurological Devices

Number K051615