K072327

Regeneration™ TECHNOLOGIES, INC.
11621 Research Circle
Post Office Box 2650
Alachua, FL 32616-2650
USA
Tel 386.418.8888
Toll Free 877.343.6832
Fax 386.418.0342
www.rtix.com

Attachment 4: 510(K) Summary

August 17, 2007

OCT 2 4 2007

Submitted by: Lisa Simpson
Regeneration Technologies, Inc.
11621 Research Circle
Alachua, FL 32615
Phone: 386-418-8888 x4326
Fax: 386-418-1627

Proprietary Name: CANCELLO-PURE™ Wedge

Common Name: Filler, bone void, calcium compound

Product Code: MQV, Orthopedics Panel

Code Section: 21 CFR 888.3045

Substantial Equivalence:
The CANCELLO-PURE™ Wedge is substantially equivalent to predicate devices in materials, design, and function.

Description:
The CANCELLO-PURE™ Wedge is machined into a wedge shape from bovine bone processed with the BioCleanse® Tissue Sterilization Process. These products are pre-shaped for surgeon convenience.

Intended Use:
These products 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:
The CANCELLO-PURE™ Wedge has materials, design and function equivalent to predicate devices. The source of bovine bone used in the manufacture of these products is a closed herd located in the U.S.A.

The BioCleanse® Tissue Sterilization Process, used in the manufacture of these products, has been shown to render processed bovine bone capable of remodeling comparably to

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allograft in an animal model. A viral inactivation study using a worst-case representation of the BioCleanse® process has shown reduction of a panel of viruses to below detectable limits.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Regeneration Technologies, Inc.
% Ms. Lisa Simpson
11621 Research Circle
P. O. Box 2650
Alachua, FL 32616-2650

OCT 2 4 2007

Re: K072327
Trade/Device Name: Cancello-Pure™ Wedge
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: September 20, 2007
Received: September 24, 2007

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 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

Attachment 2: Indications for Use

510(k) Number (if known): _____

Device Name: CANCELLO-PURE™ Wedge

Indications for Use:

These products 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___ 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 K072327