Regeneration™
TECHNOLOGIES, INC.

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FEB 16 2005

510(K) Summary

K 043421

Date: December 9, 2004

Submitted by: Carrie Hartill
Regeneration Technologies, Inc.
11621 Research Circle
P.O. Box 2650
Alachua, FL 32616-2650
Telephone: 386-418-8888
Facsimile: 386-462-3821

Proprietary Name:
OPTEFORM® Allograft Full Disk
OPTEFORM® Allograft Partial Disk
OPTEFORM® Moldable Allograft Paste, Syringe
OPTEFORM® RT Allograft Paste
OSTEOFIL® IC Moldable Allograft Syringe
OSTEOFIL® ICM Moldable Strip
OSTEOFIL® RT ICM Moldable Allograft
RTI Allograft Paste IC
RTI Allograft Strip IC

Common Name:
Bone Void Filler

Classification Name:
Filler, Calcium Sulfate Preformed Pellets (per 21CFR section 888.3045)

Predicate Devices:
The current devices have the same indications as and are substantially equivalent to the Pro Osteon™ Implant 500R Resorbable Bone Void Filler.

Description:
These devices are bone paste products made by combining gelatin, demineralized bone matrix and cortical-cancellous bone chips.

Indications for Use:
OPTEFORM® Allograft Full Disk; OPTEFORM® Allograft Partial Disk; OPTEFORM® Moldable Allograft Paste, Syringe; OPTEFORM® RT Allograft Paste; OSTEOFIL® IC Moldable Allograft Syringe; OSTEOFIL® ICM Moldable Strip; OSTEOFIL® RT ICM Moldable Allograft; RTI Allograft Paste IC; and RTI Allograft Strip IC 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., the extremities, spine and 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 remodels into the recipient's skeletal system.

Summary of Technological Characteristics:
These devices are composed of allograft demineralized bone and cortical-cancellous bone chips in a gelatin carrier matrix. These devices have been screened for osteoinductivity in an *in vivo* assay[1] and also provide a scaffold for osteoconduction. The processed coral in the Pro Osteon® Implant 500R Resorbable Bone Void Filler provides a scaffold for osteoconduction.

Non-Clinical Performance Data Supporting Substantial Equivalence Determination:
Results from studies in animal models indicate that these products can be used as a bone void filler with equivalent or better healing results when compared to the predicate device. Healing was evaluated radiographically, histologically, and mechanically.

[1] DBM and finished product were screened for osteoinductivity in a rat assay. Findings from an animal model are not necessarily predictive of human clinical results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 16 2005

Ms. Carrie Hartill
Vice President of Quality Assurance and Regulatory Affairs
Regeneration Technologies, Inc.
11621 Research Circle
P.O. Box 2650
Alachua, Florida 32616-2650

Re: K043421
Trade Name: OPTEFORM® Allograft Full Disk, OPTEFORM® Allograft Partial Disk, OPTEFORM® Moldable Allograft Paste, syringe, OPTEFORM® RT Allograft Paste, OSTEFOIL® IC Moldable Allograft Syringe, OSTEFOIL® ICM Moldable Strip, OSTEFOIL® RT ICM Moldable Allograft, RTI Allograft Paste IC, RTI Allograft Strip IC
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: February 4, 2005
Received: February 7, 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,

Celia M. Witten, Ph. D, M.D.
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): K 043421

Device Name:

OPTEFORM® Allograft Full Disk
OPTEFORM® Allograft Partial Disk
OPTEFORM® Moldable Allograft Paste, Syringe
OPTEFORM® RT Allograft Paste
OSTEOFIL® IC Moldable Allograft Syringe
OSTEOFIL® ICM Moldable Strip
OSTEOFIL® RT ICM Moldable Allograft
RTI Allograft Paste IC
RTI Allograft Strip IC

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 (i.e., the extremities, spine and 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 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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K043421