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

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510(K) Summary

Date: March 24, 2005

Submitted by: Carrie Hartill
Regeneration Technologies, Inc.
11621 Research Circle
Alachua, FL 32615
Phone: 386-418-8888 x4382
Fax: 386-462-3821

Proprietary Name:
STERLING® Interference Screw ST

Common Name:
Screw, fixation, bone

Classification:
HWC, orthopedics panel

Code Section:
21 CFR 888.3040

Substantial Equivalence:
The STERLING® Interference Screw ST is substantially equivalent to the Bioscrew Absorbable Interference Screw in design and function, and substantially equivalent to BioOss Anorganic Bovine Bone in materials.

Description:
The STERLING® Interference Screw ST is machined from processed bovine cortical bone, with lengths ranging from 15 to 40mm and diameters ranging from 7 to 10 mm. The STERLING® Interference Screw ST is threaded, has an internal hex-drive, and has a rounded proximal head.

Intended Use:
The STERLING® Interference Screw ST is intended for use in an arthroscopic or open ACL and/or PCL reconstruction by a trained medical professional.

Summary of Technological Characteristics:
The STERLING® Interference Screw ST and the BioScrew Absorbable Interference Screw have substantially equivalent design and function, but different materials. The STERLING® Interference Screw ST is constructed of bovine bone and is substantially equivalent in materials to another 510(k)-cleared product, BioOss Anorganic Bovine Bone.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 9 - 2005

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

Re: K050767
Trade/Device Name: STERLING® Interference Screw ST
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: March 24, 2005
Received: March 25, 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 may be obtained 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,

for Miriam Provost, Ph.D.
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): K050767

Device Name: STERLING® Interference Screw ST

Indications for Use: The STERLING® Interference Screw ST is used to provide interference fixation of femoral and/or tibial tunnels in anterior cruciate ligament reconstruction using a soft tissue graft; fixation during posterior cruciate ligament reconstruction utilizing a soft tissue graft.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___No___ (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 K050767