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510(k) Summary

ArthroCare Corporation
Atlantech Graft Fixation Screw

General Information

Submitter Name/Address:	ArthroCare Corporation 680 Vaqueros Avenue Sunnyvale, CA 94085-2936
Phone Number:	(408) 736-0224
Contact Person:	Valerie Defiesta-Ng Director, Regulatory Affairs
Manufacturers Name/Address:	Atlantech Medical Devices, Ltd. (Subsidiary of ArthroCare Corporation) Atlantech House, 38 Freemans Way Harrogate Business Park, Harrogate North Yorkshire, HG3 IDH United Kingdom
Date Prepared:	June 16, 2003

Device Description

Trade Name:	Atlantech Graft Fixation Screw
Generic/Common Name:	Screws, Fixation, Bone
Classification Name:	Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040)

Predicate Devices

RCI Fixation Screws	K992945, cleared November 18, 1999
Arthrex Cannulated Interference Screw	K915424, cleared February 9, 1993

Product Description

The Atlantech Graft Fixation Screw is for fixation of grafts in cruciate ligament reconstructive surgery. Standard features include a tapered rear profile, which minimizes graft impingement post implantation. The screw is cannulated to accept 1.2mm A-Tech Controlled Flexion Guidewire.

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Intended Uses

The Atlantech Graft Fixation Screw is an interference screw for use in the fixation of bone-tendon-bone grafts in cruciate ligament reconstructive surgery.

Substantial Equivalence

Based on the indications for use statement and technological characteristics to the predicate devices, the Atlantech Graft Fixation Screw is substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.

Summary of Safety and Effectiveness

The Atlantech Graft Fixation Screw, as described in this 510(k), is substantially equivalent to the predicate device with respect to the indications for use and technological characteristics. The use of interference screws for the fixation of grafts in cruciate ligament reconstructive surgery is well established. Atlantech Graft Fixation Screws have been commercially available in Europe since 1996 and do not differ markedly from others on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 4 2003

Ms. Valerie Defiesta-Ng
Director, Regulatory Affairs
ArthroCare Corporation
680 Vaqueros Avenue
Sunnyvale, California 94085-2936

Re: K031937
Trade/Device Name: Atlantech Graft Fixation Screw
Regulation Numbers: 21 CFR 888.3040
Regulation Names: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Codes: HWC
Dated: June 16, 2003
Received: June 24, 2003

Dear Ms. Defiesta-Ng:

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.

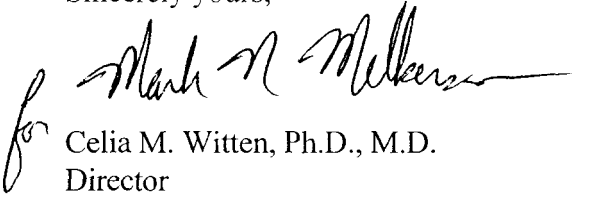
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4659. 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/dsma/dsmamain.html

Sincerely yours,



for 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 Statement

Device Name Atlantech Graft Fixation Screw

510(k) Number: K 031937

Indications for Use:

The Atlantech Graft Fixation Screw is an interference screw for use in the fixation of bone-tendon-bone grafts in cruciate ligament reconstructive surgery.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use	X	OR	Over-the-Counter Use	

(Per 21 CFR 801.109)

for Mark N Milhern

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

510(k) Number K031937