ARC SURGICAL

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510(k) Summary

SEP 19 2006

This summary regarding 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitter Information: Arc Surgical LLC
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USA
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Contact: Ed Boehmer, Regulatory Supervisor

Classification Name:	Smooth or threaded metallic bone fixation fastener
Common Name:	Screw, Fixation, Bone
Proprietary Name:	Arc Surgical **Biotrak**™ Screw System
Proposed Regulatory Class:	Class II, 21 CFR 888.3040
Device Product Code:	HWC
Legally Marketed Equivalent Device(s):	Arthrex Bio-Compression Screw K032098
	Bionx Smart Screw K003077
	Biomet ReUnite Bone Screw K992301

Device Description: The ARC Surgical **Biotrak**™ Screw System is composed of screws injection molded from poly-L-lactic acid (PLLA) with diameter (4.3mm to 4.8mm) and length (16mm to 24mm). Headless screw compression is obtained from the variable pitch of the threads. The screws are provided sterile.

Intended Use: The **Biotrak**™ resorbable compression screw is intended to provide fixation and/or reduction of small bone fractures, osteotomies, and arthrodeses, cancellous fragments, and osteochondral fragments in the upper and lower extremities. Specifically, these indications include osteochondral defects (OCDs), patella rim fractures, tarsal fractures, metatarsal fusions and fractures, metatarsal osteotomies, hallux valgus corrections, humeral condyle fractures, metacarpal fusions and fractures, carpal fusions and fractures, radial head fractures, and distal radius fractures.

These are similar to the intended use of predicate devices and do not raise new issues of safety and effectiveness.

Technological Characteristics: The screws are being injection molded from PLLA pellets (Boehringer-Ingleheim Resomer 210S). The PLLA pellets are polymerized from L-lactide monomers through the process of ring-opening polymerization. Stannous (tin) octoate is utilized as the catalyst. The predicates devices listed use either PLLA or LactoSorb (82% PLLA/18%PGA).

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Performance data is included in Section 10.
A discussion of clinical and non-clinical tests is not applicable.

Based upon the similarities of the ARC Surgical **biotrak**™ Screw System and the predicate devices studied, the safety and effectiveness of the ARC Surgical **biotrak**™ Screw System is substantially equivalent to the predicate devices referenced.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 19 2006

Arc Surgical LLC
% Mr. Ed Boehmer
Regulatory Supervisor
21300 NW Jacobson Road
Hillsboro, Oregon 97124

Re: K061763
Trade/Device Name: Arc Surgical BIOTRAK™ Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: August 10, 2006
Received: August 14, 2006

Dear Mr. Boehmer:

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" (21 CFR 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 240-276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Boehmer
for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K061763

Device Name: Arc Surgical biotrak™ Screw System

Indications For Use:

The Biotrak™ resorbable compression screw is intended to provide fixation and/or reduction of small bone fractures, osteotomies, and arthrodeses, cancellous fragments, and osteochondral fragments in the upper and lower extremities. Specifically, these indications include osteochondral defects (OCDs), patella rim fractures, tarsal fractures, metatarsal fusions and fractures, metatarsal osteotomies, hallux valgus corrections, humeral condyle fractures, metacarpal fusions and fractures, carpal fusions and fractures, radial head fractures, and distal radius fractures.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use No (Part 21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Brem MD

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

510(k) Number K061763