K043176 page 1 of 2

JUN 17 2005

# ARc SURGICAL LLCr

5885 N.W. Cornelius Pass Road Suite 100
Hillsboro, Oregon 97124

Tel (503) 645-9300

## 510(k) Summary

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
5885 N.W. Cornelius Pass Road, Suite 100
Hillsboro, OR 97124
USA
Phone: (503) 645-9300
FAX: (503) 645-9304
Contact: Ed Boehmer, Regulatory Supervisor

| | |
|---|---|
| Classification Name: | Smooth or threaded metallic bone fixation fastener |
| Common Name: | Screw, Fixation, Bone |
| Proprietary Name: | Arc Surgical Resorbable Compression 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 Resorbable Compression 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 varying pitch of the threads. The headless screw has a tapered square cannulation and the driver has a square-shaped geometry to drive the screw. The screws are provided sterile.

Intended Use: The ARC Surgical Resorbable Compression Screw is a bioabsorbable PLLA screw intended to provide fixation and/or reduction of bone fragments and bones. Specifically, as listed below, the screw is intended to fix osteochondral fragments, osteotomies and fractures in the foot, and limited fractures in the wrist, elbow, and ankle.

- Osteochondral fragments
  - Femoral condyle
  - Talus
  - Navicular
- Hallux Valgus correction
- Tarsal fractures
- Distal Radius fractures
- Radial Head fractures

These are similar to 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).

*An assessment of performance data is not applicable.*
*A discussion of clinical and non-clinical tests is not applicable.*

Based upon the similarities of the ARC Surgical Resorbable Compression Screw System and the predicate devices studied, the safety and effectiveness of the ARC Surgical Resorbable Compression 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

JUN 17 2005

Mr. Ed Boehmer
ARC Surgical LLC
5885 N.W. Cornelius Pass Road, Suite 100
Hillsboro, Oregon 97229

Re: K043176
Trade/Device Name: Arc Surgical Resorbable Compression Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: May 9, 2005
Received: May 10, 2005

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" (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,

Miriam Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K043176

Device Name: Arc Surgical Resorbable Compression Screw System

Indications For Use:

The Arc Surgical Resorbable Compression Screw System is intended to fix osteochondral fragments, osteotomies and fractures in the foot, and limited fractures in the wrist, elbow, and ankle, as listed:

- Osteochondral fragments
  - Femoral condyle
  - Talus
  - Navicular
- Hallux Valgus correction
- Tarsal fractures
- Distal Radius fractures
- Radial Head fractures

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

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

510(k) K043176