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phone: (503) 645-9300 / fax: (503) 645-9304 / web: www.arcsurgical.com

**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  
21300 NW Jacobson Rd  
Hillsboro, OR 97124  
USA  
Phone: (503) 645-9300  
Fax: (503) 645-9304  
Contact: Ed Boehmer, Regulatory Supervisor

DEC 19 2007

Classification Name: Bone Fixation Pin  
Common Name: Bioabsorbable Bone Fixation Pin  
Proprietary Name: ARC Surgical BIOTRAK™ Pin System  
Proposed Regulatory Class: Class II, 21 CFR 888.3040  
Device Product Code: HTY  
Legally Marketed Equivalent Device(s): Linvatec Biomaterials Ltd. SmartPin (K041288)  
Biomet, Inc. Resorbable Bone Pins (K011522)  
Arthrex, Inc. Bio-Pin (K050259)  
Arthrex, Inc. Chondral Dart (K991971)

Device Description: The ARC Surgical BIOTRAK™ Pin System is composed of pins injection molded from poly-L-lactic acid (PLLA) with diameter 1.5mm to 2.0mm and length 20mm to 40mm. External features on the pin provide increased resistance to loosening of bone fragments. The screws are provided sterile.

Intended Use: The BIOTRAK™ Pin is intended for use in fixation and/or alignment of fragments and fractures of non-load bearing bones, osteotomies, arthrodeses, cancellous fragments, and osteochondral fragments in the upper and lower extremities.

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

Technological Characteristics: The pins are being injection molded from PLLA pellets (Boehringer-Ingelheim 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, PLA/PGA mix.

*A discussion of clinical and non-clinical tests is not applicable.*

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Based upon the similarities of the ARC Surgical BIOTRAK™ Pin System and the predicate devices studied, the safety and effectiveness of the BIOTRAK™ Pin 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

ARC Surgical, LLC  
% Mr. Ed Boehmer  
21300 NW Jacobson Road  
Hillsboro, OR 97124

DEC 19 2007

Re: K071616  
Trade/Device Name: ARC Surgical BIOTRAK PIN System  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth or threaded metallic bone fixation fastener  
Regulatory Class: II  
Product Code: HTY  
Dated: December 5, 2007  
Received: December 6, 2007

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.

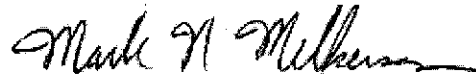
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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,



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

Enclosure

K071616

### Indications For Use

510(k) Number (if known):

Device Name: ARC Surgical BIOTRAK™ Pin System

Indications For Use:

The BIOTRAK™ Pin is intended for use in fixation and/or alignment of fragments and fractures of non-load bearing bones, osteotomies, arthrodeses, cancellous fragments, and osteochondral fragments in the upper and lower extremities.

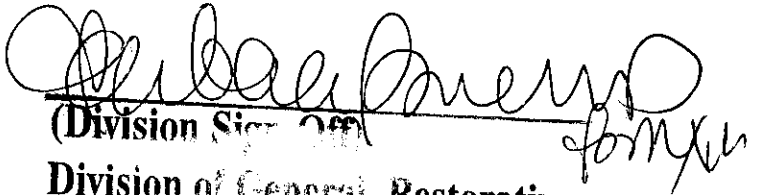
Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(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**

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