JAN - 6 1998

K973849

510(K) SUMMARY FOR THE BIONX IMPLANTS, INC.

BIOABSORBABLE BANKART TACK

Submitter's Name, Address, Telephone Number, And Contact Person

Bionx Implants, Inc.
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Date Prepared

October 7, 1997

Name of the Device

Bioabsorbable Bankart Tack

Common or Usual Name

Bionx Bankart Tack

Classification Name

Biodegradable Soft Tissue Fixation Fastener

Predicate Device

Acufex Microsurgical Inc. Suretac® Polyglyconate Absorbable Fixator (K911837)

DePuy, Inc. DuPont Phantom Suture Anchor (K964521)

Intended Use

The Bionx Bankart Tack is an absorbable device which is intended for use to maintain the proximity between soft tissue and bone to facilitate soft tissue reattachment in the repair of shoulder injuries. The Bionx Bankart Tack will be specifically indicated for use to provide internal fixation of soft tissue to bone for repair of anterior shoulder instability by reattachment of the glenoid labrum and/or inferior glenohumeral ligament in patients with primary or recurrent anterior dislocation or subluxation of the shoulder (*i.e.,* Bankart lesions). When used in conjunction with appropriate postoperative immobilization, the Bionx Bankart Tack provides secure tissue stabilization throughout the healing period.

Principles of Operation

The Bionx Bankart Tack may be used in either open or arthroscopic surgical procedures. To use the Bionx Bankart Tack, the surgeon must first examine the shoulder joint to identify the site of the labral detachment, note any stretching within the capsule and ligaments, and ascertain the degree and direction of the instability. After the damaged soft tissue is properly aligned for reattachment to the bone, the Bionx Bankart Tack is then inserted through the labrum into a predrilled hole over a guide wire. The guide wire is removed, and the position of the tack is examined anteriorly to ensure that the soft tissue is securely fixed to the bone. Substantially the same approach is followed to insert the Acufex Suretac, and similar techniques are used to insert the DuPont Phantom.

Technical Characteristics

The Bionx Bankart Tack, the Acufex Suretac, and the DuPont Phantom are intended for use in the fixation of soft tissue to bone in the repair of shoulder injuries. The Bankart Tack is a cannulated tack with a round head and four circumferential rows of scaled edges along the distal end to securely fix the tack in the bone. Like the Bionx Bankart Tack, the Acufex Suretac is a cannulated tack with a round head; however, the Suretac utilizes three raised rings along the circumference of the tack located in the middle of the shaft to fix the tack in the bone, as opposed to the scaled edges utilized by the Bankart Tack. The DuPont Phantom is secured in the bone by threading.

The Bionx Bankart Tack has substantially the same design configuration as the predicates with the exception of having scaled edges as opposed to raised rings or threading to secure the tack in the bone, and slightly different dimensions. These minor differences in design configuration do not raise any new issues of safety and effectiveness because all of the devices are secured in the bone by the same mechanism. Moreover, the question of whether the method of securing the device in the bone is sufficiently strong for this intended use is common to all of the devices.

To ensure proper alignment and fixation, the devices are each supplied with several customized insertion tools. The accompanying tools for both the Bankart Tack and the Suretac are substantially the same, and both sets of tools are

manufactured from stainless steel and plastic. The minor differences in the insertion tools of the Bionx Bankart Tack and the Acufex Suretac do not raise any new issues of safety and effectiveness because the principles of operation and method of insertion of the two devices is the same. Additionally, performance testing and clinical studies have demonstrated that the insertion technique for the Bionx Bankart Tack provides adequate fixation for this intended use.

All of the devices are manufactured from absorbable polymers which degrade over time and are absorbed by the body. The Bionx Bankart Tack and the DuPont Phantom are made of poly-L-lactide (PLLA) polymer, while the Acufex Suretac is made of polyglyconate, which is a copolymer of polyglycolic acid and trimethylene carbonate. Both the PLLA and polyglyconate materials are biocompatible and possess sufficient strength for this intended use, as demonstrated in clinical studies and performance testing. Additionally, Bionx has previously received clearance from FDA to market other implanted pins and rods made from the same PLLA polymer used in the Bionx Bankart Tack.

Summary Basis for the Finding of Substantial Equivalence

Like the previously cleared Acufex Suretac and DuPont Phantom, the Bionx Bankart Tack is intended for use to reattach soft tissue to bone in the repair of shoulder injuries. All of the devices are specifically indicated for use in the repair of Bankart lesions. Furthermore, all of the devices have very similar principles of operation and technical characteristics. The minor differences in the technical characteristics of the devices do not raise new questions of safety or effectiveness, as

confirmed by performance testing and clinical studies. Thus, the devices are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Re: K973849
Trade Name: Bioabsorbable Bankart Tack
Regulatory Class: II
Product Codes: MAI and HWC
Dated: October 8, 1997
Received: October 8, 1997

Dear Mr. Kahan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

510(k) Number (if known): K973849

Device Name: Bionx Bankart Tack

Indications For Use:

The Bionx Bankart Tack is intended for use to maintain the proximity between soft tissue and bone to facilitate soft tissue reattachment in the repair of shoulder injuries. The Bionx Bankart Tack will be specifically indicated for use to provide internal fixation of soft tissue to bone for repair of anterior shoulder instability by reattachment of the glenoid labrum and/or inferior glenohumeral ligament in patients with primary or recurrent anterior dislocation or subluxation of the shoulder (*i.e.*, Bankart lesions).

(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 Devices
510(k) Number K973849

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)