K972783

510(K) SUMMARY FOR THE BIONX IMPLANTS, INC. BIODEGRADABLE THREADED SUTURE ANCHOR

APR 14 1998

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

Bionx Implants, Inc.
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Date Prepared

February 27, 1998

Name of the Device

Bionx Biodegradable Threaded Suture Anchor

Common or Usual Name

Bionx Suture Anchor

Classification Name

Biodegradable Soft Tissue Fixation Fastener

Predicate Devices

(1) American Medical Electronics, Inc. Ogden Anchor (K950875)

(2) Zimmer, Inc. Statak® Soft Tissue Attachment Device (K962397)

(3) Arthrex, Inc. FASTak™ Suture Anchor (K960516)

(4) Mitek Surgical Products, Inc. GII Anchor (K953877)

(5) Smith & Nephew Endoscopy, Inc. Acufex® TAG Suture Anchor (K961555)

Indications for Use

The Bionx Suture Anchor is indicated for use in arthroscopic or open surgical procedures to reattach ligaments to the shoulder bone, *i.e.*, for repair of Bankart lesions or rotator cuff tears. The device may be attached to either the articular facet surface or to metaphyseal region of the bone, provided that the thickness of the cortex is less than 1.5 mm.

Principles of Operation

The Bionx Suture Anchor is a threaded screw with a square head which is 15 mm in length and 3.8 mm in diameter. The design of the screw incorporates two channels which are cut transversely through the threads on opposite sides of the device to create a groove to hold the suture. To use the suture anchor, the surgeon first prepares the implantation site by drilling a 3.5 mm hole through the cortical bone into the cancellous bone. The surgeon then inserts the square head of the anchor into the square recess on the end of the insertion tool; an interference fit securely holds the anchor in place. A suture is then placed into the channels on either side of the anchor, threaded through a groove in the insertion tool's shaft, and held in place in a slot on the insertion tool's handle. The surgeon rotates the driver to screw the anchor into the hole and uses the suture to secure the ruptured ligament to the bone at the site of the anchor insertion. The ligament remains secured to the bone throughout the healing period, after which the anchor

gradually degrades and is completely absorbed by the body. Thus, there is no need to surgically remove the anchor.

Technical Characteristics

The Bionx Suture Anchor, the American Medical Electronics, Inc. Ogden Anchor ("Ogden"), the Zimmer, Inc. Statak® Soft Tissue Attachment Device ("Statak®"), the Arthrex, Inc. FASTak™ Suture Anchor ("FASTak™"), the Mitek Surgical Products, Inc. GII Anchor ("Mitek GII"), and the Smith & Nephew Endoscopy, Inc. Acufex® TAG Suture Anchor ("Acufex® TAG") possess similar technical characteristics. All of these devices are intended for use to anchor sutures to the bone in orthopedic surgical procedures to reattach soft tissue to bone. The Bionx Suture Anchor, the Ogden, the Statak®, and the FASTak™ are all screw anchors, while the Mitek GII is a "barbed" anchor, and the Acufex® TAG is a wedge shaped anchor. However, this difference in configuration does not raise any new questions of safety or effectiveness because the devices incorporate similar features to ensure that they remain fixed in the bone. In addition, although the Bionx Suture Anchor is made of biodegradable polylactide polymers, while the Ogden, the Statak®, the Mitek GII, and the FASTak™ are composed of titanium, and the Acufex® TAG is composed of biodegradable polyglyconate, this difference in materials does not raise any new questions of safety or effectiveness. The polylactide materials used in the Bionx Suture Anchor are substantially the same as the materials that have been used in other previously cleared implantable devices. Moreover, the biocompatibility of these materials has been established in the medical literature, and all of the materials possess sufficient strength for soft

tissue repair. Performance data confirms that the Bionx Suture Anchor possesses adequate pullout strength and torsional strength for its intended use.

Summary Basis for the Finding of Substantial Equivalence

Like the previously cleared Ogden, the Statak®, the FASTak™, the Mitek GII, and the Acufex® TAG, the Bionx Suture Anchor is intended for use to anchor the suture to the bone in orthopedic procedures to reattach soft tissue to bone in the shoulder. Furthermore, all of the suture anchors possess similar principles of operation and technical characteristics. The minor differences in the technical characteristics of the two devices, such as differences in the configuration, do not raise new questions of safety or effectiveness, as confirmed by performance testing. Thus, the devices are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 14 1998

Mr. Jonathan S. Kahan
Partner
Hogan & Hartson, L.L.P.
Representing Bionx Implants, Inc.
Columbia Square
555 Thirteenth Street, NW
Washington, D.C. 20004-1109

Re: K972783
Bionx Biodegradable, Threaded Suture Anchor
Regulatory Class: II
Product Code: MAI and HWC
Dated: January 30, 1998
Received: January 30, 1998

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.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):_____

Device Name: Bionx Biodegradable Threaded Suture Anchor

Indications For Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Stephen Rhodes

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972783

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

(Optional Format 1-2-96)