K972326

510 (k) SUMMARY - SAFETY and EFFECTIVENESS

FEB 6 1998

Submitted by: Jeffrey P. Baldwin
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Contact: Jeffry B. Skiba, Vice President of Engineering & Manufacturing

Date of preparation: October 1, 1997

Name: Anchor/Suture Combination
Proprietary Name: PeBA Anchor/Suture Combination, Cinch Anchor/Suture Combination
Common or usual name: Anchor/Suture Combination
Regulatory Class: Class II

Since this submission deals with suture anchor of varying size, each size must be compared to legally marketed devices of reasonably equivalent size. See table on page 2 of this packet.

Proposed Device	Equivalent Device
PeBA S 2.8 mm Anchor	Zimmer's Statak 2.5
PeBA C 4.0 mm Anchor	Arthrex's Corkscrew 5.0
PeBA RCR 5.0 mm Anchor*	Arthrex's Corkscrew 5.0
PeBA C 6.8 mm Anchor	Arthrex's Corkscrew 5.0

The proposed device, Anchor/Suture Combination is a pre-packaged, sterile device composed of a suture anchor, anchor inserter, and non-absorbable sutures. The device shall be used to secure soft tissue to bone. The device is pre-packaged so that the suture is looped through the anchor eyelet and the anchor/suture is installed in the inserter. The anchor implant site shall be prepared with an appropriate OBL drill. The inserter is used to screw the anchor into the implant site. After the anchor is fully seated, the inserter is removed from the implant site, leaving the anchor in the bone and suture looped through the anchor.

All OBL anchors are marketed through K951451. The proposed device uses these 510K approved anchors and has identical Indications For Use as the 510K approved anchors.

The suture used in the proposed device is a braided polyester suture provided by Surgical Specialties and is currently market through N80950.

The scientific basis for the device includes that the anchor is constructed as a screw with a means for suture to be secured to the thread body. When the threads are fully seated and the suture is secured to soft tissue, the anchor and suture shall be in tension to hold the soft tissue to the bone.

The proposed device is constructed from the following materials. The anchor is made of titanium alloy TI6Al4VELI. The suture is multifilament, braided, non-absorbable poly(ethylene terephthalate) surgical suture meeting USP requirements. The inserter shaft is a 300 series, 400 series, 17Cr-4Ni, or other alloy stainless steel.

Please find the two attached "Package Inserts." OBL's anchors are marketed two ways: anchors for bladder neck suspension procedures, and anchors for orthopaedic uses other than bladder neck suspension procedures. The anchors marketed for bladder neck suspension procedures are sold under the name, Cinch™. The anchors that are marketed for orthopaedic procedures other than bladder neck suspension procedures are sold under the name, PeBA® Series. Likewise, the anchor/suture combination will be sold as separate devices: The Cinch™ anchor/suture combination for bladder neck suspensions and the PeBA anchor/suture combination for the following indications:

Indications For Use:
This device (PeBA Series and Cinch Series Anchor/Suture Combination) is intended for use only for the fixation of non-absorbable synthetic sutures.

The Cinch Series Anchor/Suture Combination is intended only for the fixation of surgical suture material to the pelvis for the purpose of bladder neck suspensions for female urinary incontinence due to urethral hypermobility of intrinsic sphincter deficiency.

The PeBA Series Anchor/Suture Combination is intended for the fixation of surgical suture material for the following indications:

Shoulder:
1. Bankart lesion repairs
2. SLAP lesion repairs
3. Acromio-clavicular separation repairs
4. Rotator cuff tear repairs
5. Capsular shift or capsulolabral reconstructions
6. Biceps tenodesis
7. Deltoid repairs

Foot and Ankle:
1. Hallux Valgus repairs
2. Medial or lateral instability repairs/reconstructions
3. Achilles tendon repairs/reconstructions
4. Midfoot reconstructions
5. Metatarsal ligament/tendon repairs/reconstructions

Elbow, Wrist, and Hand:
1. Scapholunate ligament reconstructions

2. Ulnar or radial collateral ligament reconstructions
3. Tennis elbow repair
4. Biceps tendon reattachment

Knee:

1. Extra-capsular repairs:
   a. medial collateral ligament
   b. lateral collateral ligament
   c. posterior oblique ligament
2. Iliotibial band tenodesis
3. Patellar realignment and tendon repairs, including vastus medialis obliquous advancement

Following are tables of comparison and contrast between the PeBA Anchors and the predicate devices listed in the table on page 2 of this packet.

PeBA S 2.8 mm Anchor compared to the Zimmer Statak 2.5

Characteristic	PeBA S 2.8 mm Anchor	Zimmer Statak 2.5 Anchor
Anchor material	Titanium	Titanium
Inserter material	Stainless Steel	Stainless Steel
Suture material	Braided Polyester	Braided Polyester
Method of insertion	Inserter/anchor interface hexagonal. Inserter turned to screw anchor into bone.	Inserter/anchor interface hexagonal. Inserter turned to screw anchor into bone.
Basic construction of inserter	A hardened stainless steel shaft contains the hexagonal receptacle for the anchor head. The shaft is cannulated to contain the suture.	A hardened stainless steel tip is fit into the shaft. The tip contains the hexagonal receptacle for the anchor head. The tip and shaft are cannulated to contain the suture.

PeBA S 2.8 mm Anchor contrasted to the Zimmer Statak 2.5

Characteristic	PeBA S 2.8 mm Anchor	Zimmer Statak 2.5 Anchor
Number of included sutures	1 or 2	1
Size of included suture	USP #2, #1, #0, #2-0	USP #0
Thread design	Double lead ("Hi-Lo" thread design). No drill means.	Single lead with a drill means.
Thread diameter	2.8 mm	2.5 mm

PeBA C 4.0 mm Anchor compared to the Arthrex Corkscrew 5.0 mm

Characteristic	PeBA C 4.0 mm Anchor	Arthrex Corkscrew 5.0 mm Anchor
Anchor material	Titanium	Titanium
Inserter material	Stainless Steel	Stainless Steel
Suture material	Braided Polyester	Braided Polyester
Method of insertion	Inserter/anchor interface hexagonal. Inserter turned to screw anchor into bone.	Inserter/anchor interface hexagonal. Inserter turned to screw anchor into bone.
Basic construction of inserter	A hardened stainless steel shaft contains the hexagonal receptacle for the anchor head. The shaft is cannulated to contain the suture.	A hardened stainless steel shaft contains the hexagonal receptacle for the anchor head. The shaft is cannulated to contain the suture.

PeBA C 4.0 mm Anchor contrasted to the Arthrex Corkscrew 5.0 mm

Characteristic	PeBA C 4.0 mm Anchor	Arthrex Corkscrew 5.0 mm Anchor
Number of included sutures	1 or 2	2
Size of included suture	USP #5, #2, #1, #0	USP #2
Thread design	Double lead ("Hi-Lo" thread design) No drill means..	Single lead with a drill means.
Thread diameter	2.8 mm	2.5 mm

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PeBA C 6.5 mm Anchor compared to the Arthrex Corkscrew 5.0 mm

Characteristic	PeBA C 6.5 mm Anchor	Arthrex Corkscrew 5.0 mm Anchor
Anchor material	Titanium	Titanium
Inserter material	Stainless Steel	Stainless Steel
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PeBA C 6.5 mm Anchor contrasted to the Arthrex Corkscrew 5.0 mm

Characteristic	PeBA C 6.5 mm Anchor	Arthrex Corkscrew 5.0 mm Anchor
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Size of included suture	USP #5, #2, #1, #0	USP #2
Thread design	Double lead ("Hi-Lo" thread design) No drill means.	Single lead with a drill means.
Thread diameter	2.8 mm	2.5 mm

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Jeffrey B. Skiba
Vice President of Engineering
Orthopaedic Biosystems Limited, Inc.
7320 East Butherus, Suite 206
Scottsdale, Arizona 85260

FEB - 6 1998

Re: K972326
PeBA Anchor/Suture Combination
Regulatory Class: II
Product Codes: JDR and MBI
Dated: January 6, 1998
Received: January 9, 1998

Dear Mr. Skiba:

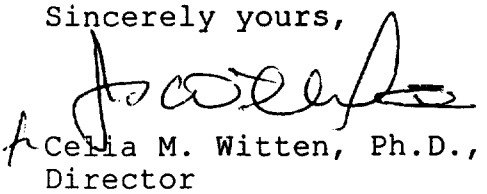
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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,



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

Appendix D: Indications for Use

510(k) Number (if known): K972326
Device Name: PEBA ANCHOR SUTURE COMBINATION

Indications For Use:
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1. Scapholunate ligament reconstructions
2. Ulnar or radial collateral ligament reconstructions
3. Tennis elbow repair
4. Biceps tendon reattachment

Knee:
1. Extra-capsular repairs:
   a. medial collateral ligament
   b. lateral collateral ligament
   c. posterior oblique ligament
2. Iliotibial band tenodesis
3. Patellar realignment and tendon repairs, including vastus medialis obliquous advancement

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 K972326

Prescription Use: X
(per 21 CFR 801.109)

OR

Over-The-Counter Use: ___

(Optional Format 1-2-96)