DEC 16

K983169

**510(k) SUMMARY**

ORTHOPAEDIC BIOSYSTEMS LTD., INC.

Date Summary was prepared: November 4, 1998

**SUBMITTER:**

Contact: Jeffrey P. Baldwin
Orthopaedic Biosystems Ltd., Inc.
15990 N. Greenway-Hayden Loop #100
Scottsdale, AZ 85260
Phone: 602-596-4066

**DEVICE:**

Name of Device: Polymer Threaded Anchor
Trade or Proprietary Name: Polymer Threaded Anchor
Common or Usual Name: Polymer Threaded Anchor
Classification Name: FASTENER, FIXATION, NONDEGRADABLE, SOFT TISSUE
Class: II

**PREDICATE DEVICE(S):**

OBL claims that the Polymer Threaded Anchor has features substantially equivalent to two 510(k) approved devices. These include: "PeBA Anchor / Suture Combination" by Orthopaedic Biosystems Ltd., Inc. (K927236) and the "2.8 and 3.5mm ROC Suture Bone Fastener" by Innovasive Devices (K963402).

**DEVICE DESCRIPTION:**

Overview

The proposed device is the "Polymer Threaded Anchor" (K983169).

The purpose of this submission is to obtain clearance for a polymer version of the "PeBA Anchor /Suture Combination" (K972326) forming a new device called, "Polymer Threaded Anchor". Changing the material used for the implant requires a 510(k) submission.

The predicate devices used for substantial equivalence comparisons include:

- "PeBA Anchor/Suture Combination" (K972326)
- "Innovasive 2.8 mm and 3.5 mm ROC Suture Bone Fastener" (K963402)

The Polymer Threaded Anchor is a modification of the "PeBA Anchor/Suture Combination". The proposed device is the same as the predicate device in terms of usage and function. The modifications include:

- Changing the material of the Anchor (implant) from Titanium alloy to Polyacetal.
- Marketing the anchor alone without suture or inserter

The Polymer Threaded Anchor uses polyacetal as the material for the anchor. Innovasive uses Polyacetal as a material in the construction of the "ROC Bone Fastener".

Device Description

The proposed device, Polymer Threaded Anchor, is a pre-packaged, sterile polyacetal implant. The device is used to secure soft tissue to bone. The device is to be used with reusable insertion devices including a drill, tap, drill/tap combination, and inserter. Surgeons may loop suture of his/her choice through the eyelet of the anchor for the attachment of soft tissue. The device is single use. The device can be used for open and arthroscopic procedures. The anchor is packaged sterile in double mylar/tyvek pouches or formed trays.

The Polymer Threaded Anchor is a polyacetal screw designed to be screwed into a hole in bone chosen by the surgeon as a site for anchoring soft tissue to bone. The anchor constists of a threaded portion to engage bone, an eyelet to retain suture, and a drive means to couple the device to the inserter. The anchor is referred to by it's major diameter (the diameter of the largest thread). The sizes included in this submission are 2.8 mm, 4.0 mm, 5.0 mm, and 6.5 mm. Please see the drawings on page 9 for shape and dimensions of the device.

The Insertion Device is a manual surgical instrument comprised of a handle and shaft. The handle is constructed from polypropylene and serves as the interface between the surgeon's hand and the device. The shaft serves the functions of transferring the torque from the surgeon's hand to the anchor.

Materials

Polyacetal

Use

To implant the Anchor, the surgeon must first create an implantation site in bone. OBL supplies accessory drills, taps and drill/tap combinations to prepare these sites. The inserter is used to screw the anchor into the implantation site. After the anchor is fully seated, the inserter is removed from the implantation site, leaving the anchor in the bone and suture through the anchor. The suture can then be used to attach soft tissue.

**INTENDED USE:**
This device (Polymer Threaded Anchor and Cinch Polymer Threaded Anchor) is intended for use only for the fixation of non-absorbable synthetic sutures.

The Polymer Threaded Series Anchor is intended for the fixation of surgical suture material for the following indications:

Shoulder:
1. Bankhart Repair
2. SLAP Lesion Repair
3. Acromio-clavicular separation
4. Rotator Cuff Repair
5. Capsule and Capsulolabral Reconstruction
6. Biceps Tenodesis
7. Deltoid Repair

Hand, Wrist, Elbow:
1. Scapholunate ligament reconstruction
2. Ulnar Collateral Ligament Reconstruction
3. Lateral Collateral Ligament Reconstruction
4. Biceps Tendon Reattachment
5. Elbow Medial/Lateral Repair of Tendons in the Elbow

Foot:
1. Hallux Valgus Reconstruction
2. Mid and Forefoot Reconstruction

Knee:
1. medial collateral ligament
2. lateral collateral ligament
3. posterior oblique ligament
4. Joint capsule closure
5. Illiotibial band tendonesis
6. VMO Advancement

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

## COMPARISON OF CHARACTERISTICS:

### OBL Polymer Threaded Anchor vs. Innovasive 2.8mm and 3.5mm ROC Suture Bone Fastener

Both devices utilize Polyacetyl as a material in the construction of the anchor. Both devices utilize suture to join soft tissue to the anchor. Both devices can be EtO sterilized.

### OBL Polymer Threaded Anchor vs. OBL PeBA Anchor / Suture Combination

Both devices follow the same method of implantation. Both anchors utilize a thread to purchase bone and provide a soft tissue fixation site. OBL offers drills, taps, and other devices for the preparation of implantation sites for both products.

## PERFORMANCE DATA

Test of Pullout Strength
The anchors were implanted in a cancellous bone model made from polyurethane foam with a density of 8 lbs/cft. The anchors were pulled until they were liberated from the foam.

The foam model is considered a worst case situation. The density of foam chosen closely approximates the density of cancellous bone. Using a substrate of uniform density provides more consistent results than using bone which can vary in density and vary in cortex thickness. By testing competitor's anchors in the foam, comparisons of pullout data can be made without respect to the density of the substrate for each datum.

All four of the proposed devices provide higher pullout strength than the predicate ROC device.

Test of Anchor/Suture Interface
The threads of the anchors were fixed and suture was looped through the eyelet. The suture was tensioned until failure occurred. Because the 2.8 anchor has the smallest head of the four anchors included in this submission, it is considered the worst case.

The knot is considered the weakest point in a suture (worst case) because of the stress risers it creates in the suture. The suture most likely to break at the knot or the anchor eyelet when loaded. A design criteria for the anchor is to create a lesser stress riser than the knot.

The Polymer OBL 2.8 mm Anchor provides higher suture break strength than USP listed Knot Break Strength for.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 1998

Mr. Jeffrey P. Baldwin
Engineering
Orthopaedic Biosystems Limited, Inc.
15990 North Greenway-Hayden Loop #100
Scottsdale, Arizona 85260

Re: K983169
Trade Name: Polymer Threaded Anchor
Regulatory Class: II
Product Codes: MBI and HWC
Dated: November 2, 1998
Received: November 27, 1998

Dear Mr. Baldwin:

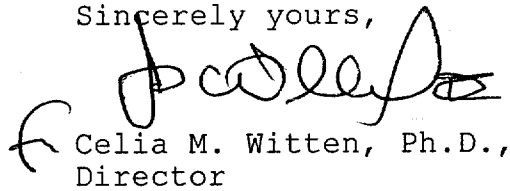
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

# STATEMENT OF INDICATIONS FOR USE

510(k) Number: K983169
Device Name: Polymer Threaded Anchor

This device (Polymer Threaded Anchor and Cinch Polymer Threaded Anchor) is intended for use only for the fixation of non-absorbable synthetic sutures.

The Polymer Threaded Anchor 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 oblivious advancement

The Cinch Polymer Threaded Anchor 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number 14831