3/4/99

K982996

510(k) SUMMARY

ORTHOPAEDIC BIOSYSTEMS LTD., INC.

Date Summary was prepared: October 20, 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 OBL SB Anchor / Suture Combination
Trade or Proprietary Name: Polymer OBL SB Anchor / Suture Combination
Common or Usual Name: Polymer SB Anchor / Suture Combination
Classification Name: FASTENER, FIXATION, NONDEGRADABLE, SOFT TISSUE
Class: II

PREDICATE DEVICE(S):

OBL claims that the Polymer OBL SB Anchor / Suture Combination has features substantially equivalent to two 510(k) approved devices. These include:

- "2.8 and 3.5mm ROC Suture Bone Fastener" by Innovasive Devices (K963402).
- "SB Bone Anchor" by Orthopaedic Biosystems Ltd., Inc (K950592)

DEVICE DESCRIPTION:

The Polymer OBL SB Anchor is a simple modified polyacetal cylinder designed to be pushed through a hole in bone chosen by the surgeon as a site for anchoring soft tissue to bone. Each anchor is preloaded with suture and includes an insertion device.. These components are packaged together sterile in double mylar/tyvek pouches or formed trays. The device is single use. The device can be used for open and arthroscopic procedures.

The anchor is a modified cylinder made of polyacetal. From the end, the anchor is round with two grooves milled 180° apart. From the side, the anchor is a parallelogram with a hole through it. The anchors will be referred to by the diameter and the overall length, for example 2x8 means the diameter is 2.0 mm and the length is 8 mm. Refer to the drawing on page 12 for the dimensions "C" and "A".

The largest anticipated size of the anchor is 3 mm in diameter and 15 mm in length (3x15). The smallest anticipated size of the anchor is 2 mm in diameter and 8 mm in length (2x8). The purpose of the hole through the device is to hold suture. The smooth longitudinal grooves on each side of the device allow the suture to pass into the bone hole without pinching the suture. The ends of the device are designed to initiate rotation of the device as it is pushed and subsequently pulled into place. The ends are tapered at angles that range from 30° to 60°. The anchor is symmetric, allowing it to be inserted with regard to which end enters first. The shape

of the device distributes the load over a large bone surface reducing the risk of bone breakage or pullout.

The Insertion Device is a manual surgical instrument comprised of a handle, sleeve, and piston. The handle is constructed from polypropylene and serves the functions of holding all pieces together and to interface between the surgeon's hand and the device. The sleeve houses the piston and the Anchor. The sleeve keeps the Anchor and piston in-line to allow the piston to push the Anchor into the implantation site.

The Suture is Braided Polyester Suture from Surgical Specialties (See Appendix 3 for Approval Letters, N80950). The largest anticipated diameter of the suture USP #2. The smallest anticipated diameter of suture is USP #2-0. The suture is preloaded in the anchor eyelet.

Materials
Anchor: Polyacetal
Inserter: Piston and Sleeve: Stainless Steel, Handle: Polypropylene
Suture: Braided Polyester from Surgical Specialties, See Appendix 3.

Use
To implant the Anchor, the surgeon must first create an implantation site in bone. OBL supplies accessory drills and awls to prepare these sites.

Once the implantation site is prepared, the surgeon simply aligns the Anchor to the hole, pushes the handle toward the bone, retracts, and disconnects the Suture from the Inserter. The Suture will be retained by the Anchor. Pulling back on the Suture further engages the Anchor into the walls of the hole. The surgeon is then left with an Anchor in the bone and Suture to attach to the soft tissue.

INTENDED USE:
This device, Polymer OBL SB Series and Cinch Series Anchor/Suture Combination is intended for use only for the fixation of non-absorbable synthetic sutures for the following indications.

The Polymer Cinch SB 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.

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

Urinary: Bladder Neck Suspension

COMPARISON OF CHARACTERISTICS:

OBL Polymer OBL SB Anchor / Suture Combination vs. OBL SB Bone Anchor

The design of the OBL Polymer OBL SB Anchor is similar to the SB Bone Anchor. The only difference between the two implants is the material. The SB Bone Anchor is constructed of Titanium Alloy Ti6Al4VELI. The OBL Polymer OBL SB Anchor is constructed from Polyacetal. The indications for use for the two products is identical.

OBL Polymer OBL SB Anchor / Suture Combination vs. Innovasive 2.8 mm and 3.5 mm ROC Suture Bone Fastener

Both devices utilize Polyacetal 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.

PERFORMANCE DATA

The anchors were tested for two physical characteristics, Pullout Strength and Suture Break Strength.

Pullout Strength was determined in a cancellous bone model. The smallest version of the proposed devices measures 2 mm by 8 mm and provides 9.6 lbs of pullout strength. The largest version of the proposed devices measures 6 mm by 15 mm and provides 14 lbs of pullout strength. By comparison, the predicate Innovasive product showed 9 lbs of pullout strength in this model.

The knot is considered the weakest part of a suture because of the stress riser it creates. The USP listed knot break strength for #2 synthetic suture is 14 lbs. The smallest version of the proposed devices handles 19.4 lbs of strength before the suture breaks. The largest version of the proposed devices handles 23.2 lbs of strength before the suture breaks. This means that as force is applied to the suture, the suture at the knot will fail before the suture at the anchor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 4 1999

Mr. Jeffrey B. Baldwin
Vice President of Engineering
Orthopaedic Biosystems Limited, Inc.
15990 North Greenway-Hayden Loop, Suite 100
Scottsdale, Arizona 85260

Re: K982996
Polymer OBL SB Suture/Anchor Combination
Regulatory Class: II
Product Codes: JDR, MBI, and GAT
Dated: December 2, 1998
Received: December 8, 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,

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

STATEMENT OF INDICATIONS FOR USE

510(k) Number: K982996
Device Name: Polymer OBL SB Anchor / Suture Combination

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6. VMO Advancement

Urinary: Bladder Neck Suspension

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Russell S. Kaymen for CAW

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982996

Prescription Use ✓
(Per 21 CFR 801.109)