



K964805

11311 Concept Boulevard Largo, Florida 33773 813 399-5334 Fax 813 399-5264

Carol A. Weideman, Ph.D.

Manager, Regulatory  
and Clinical Affairs

JUN - 9 1997

### **510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR.807.92, Linvatec Corporation is hereby submitting the 510(k) Summary of Safety and Effectiveness for the Bio-Anchor™ Absorbable Suture Anchor, 510(k) Number K964805.

**A. Submitter**

Linvatec Corporation  
11311 Concept Boulevard  
Largo, Florida 33773

**B. Company Contact**

Carol A. Weideman, Ph.D.  
Manager, Regulatory and Clinical Affairs

**C. Device Name**

Trade Name: Bio-Anchor  
Common Name: Suture Anchor  
Classification Name: Soft tissue to bone fixation device

**D. Predicate/Legally Marketed Devices**

Linvatec Preloaded Soft Tissue Anchor  
Linvatec Bio-Anchor



A Bristol-Myers Squibb Company

**E. Device Description**

The Bio-Anchor is a PLLA suture anchoring device. The device is cylindrical in shape with three circular ribs perpendicular to the long axis. The first and second ribs are the same size, with the proximal, third rib wider to allow for a centrally located eyelet running perpendicular to the long axis of the device. Freely passing suture is then threaded onto the Bio-Anchor by the surgeon. The lack of permanent attachment of the suture to the Bio-Anchor allows the use of sliding knots. Once the Bio-Anchor is implanted, the ends of the suture are passed through the soft tissue and tied for reattachment. Synthetic non-absorbable, polyester USP #0, #1, or #2 suture is recommended for use with this device.

The material used for this device is:

Anchor - Poly (L-lactic) acid (PLLA)

**F. Intended Use**

The Bio-Anchor is a bioabsorbable device used for soft tissue to bone fixation in orthopedic applications except for anterior or posterior cruciate ligament repair or reconstruction.

The Bio-Anchor Absorbable Suture Anchor is available in a 3.5mm size.

**G. Substantial Equivalence**

The Bio-Anchor Absorbable Suture Anchor is substantially equivalent in function and intended use to Linvatec's Preloaded Soft Tissue Anchor and Linvatec's Bio-Anchor. The material is identical to the original Linvatec Bio-Anchor.

The similarities/dissimilarities to the predicates are shown in the attached table.

**SUBSTANTIAL EQUIVALENCE INFORMATION:**

**CHART OF SIMILARITIES AND DISSIMILARITIES**

Company Name	Device Name	Intended Use	Material	Single-Use/ Reusable	Sizes
<b>New Product:</b>  Linvatec	Bio-Anchor	Soft tissue to bone fixation in orthopedic applications except for anterior or posterior cruciate ligament repair or reconstruction.	Poly (L-lactic) acid	Single-Use  ETO Sterilization	3.5mm diameter  Suture: USP Sizes #0 to #2
<b>Predicate:</b>  Linvatec: Preloaded Soft Tissue Anchor 510(k) # K953954	Preloaded Soft Tissue Anchor	Soft tissue to bone fixation	Titanium Alloy  Suture: Non-absorbable Braided Polyester	Single-Use  Gamma Sterilization	2.5mm - 5.2mm diameter  Suture: USP sizes #0 to #2
<b>Predicate:</b>  Linvatec: Bio-Anchor Absorbable Suture Anchor 510(k) #K955486	Bio-Anchor	Soft tissue to bone fixation	Poly (L-lactic) acid  #0, #1, or #2 Non-Absorbable Suture	Single-Use  ETO Sterilization	3.5mm diameter  Suture: USP Sizes #0 to #2



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN - 9 1997

Carol A. Weideman, Ph.D.  
Manager, Regulatory and Clinical Affairs  
Linvatec Corporation  
11311 Concept Boulevard  
Largo, Florida 34643

Re: K964805  
Bio-Anchor® Absorbable Suture Anchor  
Regulatory Class: II  
Product Code: MAI  
Dated: March 20, 1997  
Received: March 21, 1997

Dear Dr. Weideman:

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.

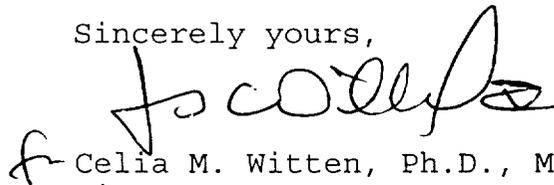
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 pre-market 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.

Page 2 - Carol A. Weideman, Ph.D.

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,

  
f 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



11311 Concept Boulevard Largo, Florida 33773-4908 813 392-6464

June 3, 1997

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510(k) Number (if known): K964805

Device Name: BIO-ANCHOR™ ABSORBABLE SUTURE ANCHOR

Indications for Use:

The Bio-Anchor is a bioabsorbable device used for soft tissue to bone fixation in orthopedic applications except for anterior or posterior cruciate ligament repair or reconstruction.

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

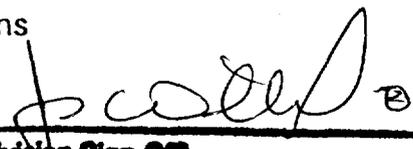
Foot and Ankle

1. Hallux Valgus repairs
2. Medial or lateral instability repairs/reconstructions
3. Achilles tendon repairs/reconstructions
4. Midfoot reconstructions

Elbow, Wrist and Hand

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

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K964805

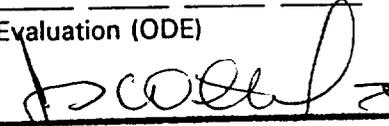


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Knee

1. Extra-capsular repairs and reattachments of:
  - a. medial collateral ligament
  - b. lateral collateral ligament
  - \* c. posterior oblique ligament or joint capsule to tibia
  - d. joint capsule closure to anterior proximal tibia
2. Extracapsular reconstruction, iliotibial band tenodesis
3. Patellar realignment and tendon repairs

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

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

K964805

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-the-Counter Use \_\_\_\_\_