OCT 21 1998

K983186

October 15,1998

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 Pre-loaded Bio-Anchor Absorbable Suture Anchor, 510(k) Number K983186.

A. Submitter

Linvatec Corporation
11311 Concept Boulevard
Largo, Florida 33773-4908

B. Company Contact

Carol A. Weideman, Ph.D.
Director, Compliance and Regulatory Affairs

C. Device Name

Trade Name:	:	Bio-Anchor, Pre-loaded Bioabsorbable Suture Anchor
Common Name	:	Suture Anchor
Classification Names	:	None Assigned
Proposed Class/Device Product Code	:	Class II, 87 MAI, Fastener Fixation, Biodegradable, Soft Tissue

D. Predicate/Legally Marketed Devices

Bio-Anchor
Linvatec Corporation

Pre-loaded Soft Tissue Anchors
Revo/Mini Revo
Linvatec Corporation

E. Device Description

The Pre-loaded Bio-Anchor is an injection molded Poly (L-lactic) acid suture anchoring device with an attached non-absorbable braided polyester suture USP size #2. The device is cylindrical in shape with three circular ribs perpendicular to the long axis. The suture is passed through the eyelet of the anchor and attached to a wire by shrink tubing.

F. Intended Use

The Pre-loaded Bio-Anchor is a bioabsorbable device with attached suture used to attach soft tissue to bone in arthroscopic or open procedures 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. Altoid 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

F. Intended Use (con't)

Knee

1. Extracapsular 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

Bladder Neck Suspension

1. Soft tissue fixation of the pubic bone for the purpose of bladder neck suspension for female urinary incontinence due to urethral hypermobility.

G. Substantial Equivalence

The Pre-loaded Bio-Anchor is substantially equivalent in design, function and intended use to the Bio-Anchor (Linvatec Corporation), and the Revo/Mini Revo Pre-loaded Suture Anchors, (Linvatec Corporation).

Testing has been done to prove safety and effectiveness of the devices.

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

CHART OF SIMILARITIES AND DISSIMILARITIES

Company	Device Name	Intended Use	Material	Single-Use Reusable	Sizes
NEW PRODUCT Linvatec	Pre-loaded Bio-Anchor Absorbable Suture Anchor	Soft tissue to bone fixation for shoulder, knee, foot, ankle, elbow, wrist, hand, and bladder neck suspension procedures.	**Anchor:** Poly (L-lactic)acid **Suture:** Non-absorbable braided polyester **Suture Sleeve:** FEP Teflon Shrink Tube, MIL-I023053/11B or Polyester Shrink Tube **Wire:** 316 Stainless Steel	Single-Use ETO Sterilization Shipped Sterile	**Anchor:** 3.5mm x 10.5mm **Suture:** USP Size #2
PREDICATE Linvatec Bio-Anchor 510(k) #K964805 #K963369	Bio-Anchor	Soft tissue to bone fixation for shoulder, knee, foot, ankle, elbow, wrist, hand, and bladder neck suspension procedures.	Poly (L-lactic)acid	Single-Use ETO Sterilization Shipped Sterile	3.5mm x 10.5mm
PREDICATE Linvatec Pre-loaded Soft Tissue Anchors 510(k) #K953954	Revo/Mini Revo	Soft tissue to bone fixation.	**Anchor:** Titanium Alloy **Suture:** Non-absorbable braided polyester **Suture Sleeve:** FEP Teflon Shrink Tube, MIL-I023053/11B or Polyester Shrink Tube **Wire:** 316 Stainless Steel	Single-Use Gamma Sterilization Shipped Sterile	**Anchors:** 2.5mm - 5.2mm **Suture:** USP Sizes #0 to #2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 21 1998

Carol A. Weideman, Ph.D.
Director, Compliance and Regulatory Affairs
Linvatec
11311 Concept Boulevard
Largo, Florida 33773

Re: K983186
Trade Name: Pre-loaded Bio-Anchor
Absorbable Suture Anchor
Regulatory Class: II
Product Codes: MAI, HWC, and GAT
Dated: September 10, 1998
Received: September 11, 1998

Dear Dr. Weideman:

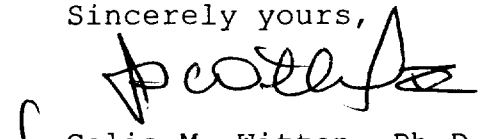
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

510(k) Number (if known): K983186

Device Name: Pre-loaded Bio-Anchor Absorbable Suture Anchor

Indications for Use:

The Pre-loaded Bio-Anchor is a bioabsorbable device with attached suture used to attach soft tissue to bone in arthroscopic or open procedures 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
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Foot and Ankle
1. Hallux Valgus repairs
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1. Scapholunate ligament reconstructions
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1. Extracapsular repairs and reattachments of:

    a. medial collateral ligament
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    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

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983186

Prescription Use X
(Per 21 CFR 801.109)

Indications for Use (con't):

Bladder Neck Suspension

1. Soft tissue fixation of the pubic bone for the purpose of bladder neck suspension for female urinary incontinence due to urethral hypermobility.

(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 K963186

Prescription Use X OR Over-the-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)