

MAY 22 1997

March 10, 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, Livatec Corporation is hereby submitting the 510(k) Summary of Safety and Effectiveness for the Bio-Anchor, 510(k) Number K963369.

A. Submitter

Livatec Corporation
11311 Concept Boulevard
Largo, Florida 33773-4908

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

Livatec Revo/Mini Revo
Mitek Gil Anchor and Absorbable Anchor
Zimmer Statak Device
Zimmer Resorbable Soft Tissue Attachment Device
Vesica Medical, Inc.

**Summary of Safety and Effectiveness
Bio-Anchor™ Absorbable Suture Anchor
510(k) # K963369
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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 Linvatec Bio-Anchor is indicated for bladder neck suspension for female urinary incontinence due to urethral hypermobility.

The Bio-Anchor Absorbable Suture Anchor is available in sizes ranging from 2.5mm to 5.2mm diameter.

G. Substantial Equivalence

The Bio-Anchor™ Absorbable Suture Anchor is substantially equivalent in function and intended use to the Mitek Surgical Products GII Anchor, Zimmer's Statak and Resorbable Soft Tissue Attachment Device, Vesica Medical's Bone Anchor System. The material is the same (PLLA) as Zimmer's Resorbable device.

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
<p>New Product</p> <p>Linvatec: Bio-Anchor</p>	Bio-Anchor	Bladder neck suspension for female urinary incontinence due to urethral hypermobility.	Poly (L-lactic) acid	Single-use ETO Sterilized Shipped sterile	2.5mm - 5.2mm diameter
<p>Products</p> <p>Linvatec: Preloaded Soft Tissue Anchors 510(k) Number K953954</p>	Revo/Mini Revo	Soft tissue to bone fixation	<p>Titanium Alloy 6Al-4V-ELI</p> <p>Suture: Non-absorbable Braided Polyester</p>	Single-use Gamma Sterilization Shipped sterile	Suture Anchor with Preloaded Suture Anchors: 2.5mm - 5.2mm Suture: USP Sizes #0 to #2
<p>Products</p> <p>Mitek: Mitek GII Anchor 510(k) Number K892126</p>	Mitek	Soft tissue to bone fixation - Bladder Neck Suspension	Titanium Alloy	Single-use Sterilization Method Unknown Shipped sterile	2.4mm X 14mm

Company Name	Device Name	Intended Use	Material	Single-Use Reusable	Sizes
<p><small>Predictors</small></p> <p>Mitek: Mitek Absorbable Anchor 510(k) Number K944051</p>	Mitek	Soft tissue to bone fixation - Bladder Neck Suspension	Poly (L-lactic) acid and Nitinol	Single-use Sterilization Method Unknown Shipped sterile	Not provided
<p><small>Predictors</small></p> <p>Zimmer: Statak Device 510(k) Number K926384</p>	Statak	Soft tissue to bone fixation - Bladder Neck Suspension	Titanium Ti-6Al-4V Alloy # 2 Braided Suture	Single-use Gamma Sterilization Shipped sterile	2.5mm - 5.2mm diameter
<p><small>Predictors</small></p> <p>Zimmer Resorbable Soft Tissue Attachment Device 510(k) Number K950275</p>	Resorbable Soft Tissue Attachment Device	Soft tissue to bone fixation	Poly (L-Lactic) Acid # 2 Braided Suture	Single-use Gamma Sterilization Shipped sterile	5.0mm - 5.2mm diameter
<p><small>Predictors</small></p> <p>Vesica Medical, Inc.: Bone Anchor System 510(k) Number K932925</p>	Bone Anchor System	Soft tissue to bone attachment for urological application - bladder neck suspension	Titanium alloy #1, #2 Suture Size	Single-use EtO Sterilization Shipped sterile	3.75mm diameter



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 1997

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

Re: K963369
Trade Name: BioAnchor™ Absorbable Suture Anchor
Regulatory Class: II
Product Code: MAI
Dated: March 10, 1997
Received: March 11, 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.

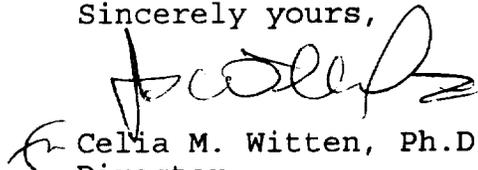
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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,



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



1311 Concept Boulevard Largo, Florida 33773-4908 813 392-6464

May 16, 1997

510(k) Number (if known): K963369

Device Name: BIO-ANCHOR™ ABSORBABLE SUTURE ANCHOR

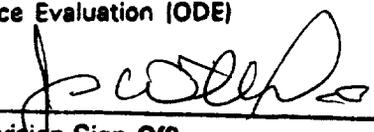
Indications for Use:

Bladder Neck Suspension

The Linvatec Bio-Anchor is indicated for 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 K963369

Prescription Use X OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)