



JUN 20 1997

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

Carol A. Weideman, Ph.D.

Manager, Regulatory
and Clinical Affairs

March 21, 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 Preloaded Soft Tissue Anchor, 510(k) Number # K963932.

A. Submitter

Linvatec 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: Revo®/Mini-Revo®
Common Name: Bone Screw
Classification Name: Soft tissue to bone fixation device

D. Predicate/Legally Marketed Devices

Mitek GII Anchor
Zimmer Statak Device



E. Device Description

The Preloaded Soft Tissue Anchor has an attached non-absorbable braided polyester suture through the eyelet. The suture is attached to a threading wire by a shrink tubing sleeve. Once the anchor is securely seated in the driver, the suture is cut on the device side of the shrink tubing and implantation can proceed.

The material used for this device is:

Anchor: Titanium Alloy
Suture: Non-absorbable braided polyester
Sleeve: Shrink tubing
Threading Wire: 316 Stainless Steel

F. Intended Use

The Preloaded Soft Tissue Anchor is a device used to attach soft tissue to bone fixation except anterior or posterior cruciate ligament repair or reconstruction. This device is indicated for bladder neck suspension for female urinary incontinence due to urethral hypermobility.

The Preloaded Soft Tissue Anchor is available in sizes ranging from 2.5mm to 5.2mm diameter.

G. Substantial Equivalence

The Preloaded Soft Tissue Anchor is substantially equivalent in function and intended use to the Mitek GII Anchor and the Zimmer Statak device. The anchors are all made of metal/metal alloy materials. Testing supports the equivalency to the predicate devices. The similarities/dissimilarities to the predicates are shown in the attached table.

SUBSTANTIAL EQUIVALENCE INFORMATION:

The similarities/dissimilarities to the predicate device/material are shown in the following table.

CHART OF SIMILARITIES AND DISSIMILARITIES

Company Name	Device Name	Intended Use	Material	Single-Use Reusable	Sizes
New Product Linvatec: Preloaded Soft Tissue Anchors	Revo/ Mini- Revo	Soft tissue to bone fixation Bladder neck suspension for female urinary incontinence due to urethral hypermobility.	Titanium Alloy 6Al-4V-ELI Suture: Non-absorbable Braided Polyester	Single-use Gamma Sterilization Shipped sterile	Suture Anchor with Preloaded Suture Anchors: 2.5mm - 5.2mm Suture: USP Sizes #0 to #2
Predicate Mitek: Mitek GII Anchor 510(k) Number K892126	Mitek	Soft tissue to bone fixation - Bladder Neck Suspension	Titanium Alloy	Single-use Sterilization Method Unknown Shipped sterile	2.4mm X 14mm
Predicate Zimmer: Statak Device 510(k) Number K926384	Statak/Mini Statak	Soft tissue to bone fixation - Bladder Neck Suspension	Titanium TI-6Al-4V Alloy Suture: Non-absorbable Braided Suture	Single-use Gamma Sterilization Shipped sterile	2.5mm - 5.2mm diameter Suture USP Sizes #0 to #2



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 20 1997

Carol A. Weideman, Ph.D.
Manager, Regulatory and Clinical Affairs
Linvatec Corporation
11311 Concept Boulevard
Largo, Florida 33773

Re: K963932
Trade Name: Revo® and Mini-Revo® Preloaded
Soft Tissue Anchor
Regulatory Class: II
Product Code: MBI
Dated: March 21, 1997
Received: March 24, 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.

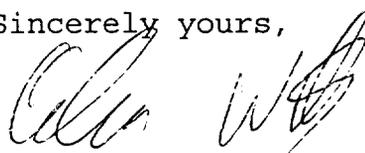
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, 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



11311 Concept Boulevard Largo, FL 34643 813 392-6464

March 21, 1997

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
CENTERS FOR MEDICAL DEVICE REGULATION

510(k) Number (if known): K963932

This information is exempt from release under Exemptions 3 and 4 of the Freedom of Information Act.

Device Name: PRELOADED SOFT TISSUE ANCHOR

Indications for Use:

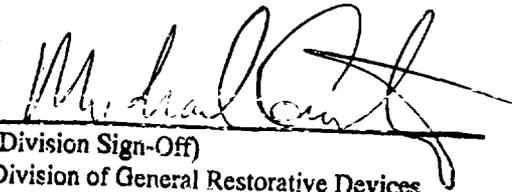
Bladder Neck Suspension

The Linvatec Preloaded Soft Tissue Anchor is indicated for bladder neck suspension for femine 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)

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


(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K963932

(Optional Format 1-2-96)