



K974538

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

Carol A. Weideman, Ph.D.

Director
Regulatory Affairs

December 2, 1997

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 Meniscal Repair Device.

A. Submitter

Linvatec Corporation
11311 Concept Boulevard
Largo, Florida 33773

B. Company Contact

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

C. Device Name

Trade Name : Meniscal Repair Device
Common Name: Bone Screw
Classification Name: Smooth or threaded metallic bone fixation fastener

D. Predicate/Legally Marketed Devices

Bionix BIOFIX SR-PLLA Meniscus Arrow.
Linvatec BioScrew® Absorbable Interference Screw

E. Device Description

The Meniscal Repair Device is a cannulated, sterile, single-use bone screw made of an absorbable homopolymer derived from Poly (L-lactic Acid) similar to that used in bioabsorbable suture and will gradually be absorbed into the body.



F. Intended Use

The Meniscal Repair Device provides fixation of longitudinal vertical meniscus lesions (bucket-handle) located in the vascularized area of the meniscus.

Implantation of the interference screw is accomplished through arthroscopy or arthrotomy.

G. Substantial Equivalence

The Meniscal Repair Device is substantially equivalent in design, function and intended use to Bionix BIOFIX SR-PLLA Meniscus Arrow. The material is the same as the Linvatec BioScrew® Absorbable Interference Screw

A comparative pull-out strength test was conducted to prove safety and effectiveness. The control device was the BIOFIX Arrow.

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

CHART OF SIMILARITIES AND DISSIMILARITIES

Company Name	Device Name	Intended Use	Material	Single-Use Reusable	Method of Sterilization	Design
New Product Linvatec	Meniscal Repair Device	Fixation of longitudinal vertical meniscus lesions (bucket handle) located in the vascularized area of the meniscus.	Poly (L-lactic Acid)	Sterile Single-use	ETO 24 month shelf life	Cannulated Barbed tack with head Sizes: 1.3mm diameter x 10mm-16mm length
Predicate Linvatec Corporation	BioScrew Absorbable Interference Screw 510(k) # K960940	Provide interference fixation in ACL and PCL reconstruction	Poly (L-lactic Acid)	Sterile Single-use	ETO 24 month shelf life	Cannulated Sizes: 7mm-9mm diameter x 20mm-30mm length
Predicate Bionix, Inc.	Biofix® SR-PLLA Meniscus Arrow 510(k) # K955768	Fixation of longitudinal vertical meniscus lesions (bucket-handle) located in the vascularized area of the meniscus.	Self-reinforced Poly (L-lactic Acid)	Sterile Single-use	Gamma 36 month shelf life	Non-cannulated Barbed tack with head Sizes: 1.1mm diameter x 10mm-16mm length



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

MAR - 3 1998

Re: K974538
Trade Name: Meniscal Repair Device
Regulatory Class: II
Product Codes: HWC and MAI
Dated: December 2, 1997
Received: December 3, 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.

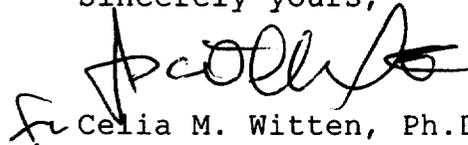
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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

Date: December 2, 1997

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510(k) Number (if known): K974538

Device Name: Meniscal Repair Device

Indications for Use:

The Meniscal Repair Device provides fixation of longitudinal vertical meniscus lesions (bucket-handle) located in the vascularized area of the meniscus.

Implantation of the device is accomplished through arthroscopy or arthrotomy.

(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 K974538

(Optional Format 1-2-96)

