K990770

JUL 30 1999

May 13, 1999

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 BioRC Anchor 510(k) Number K990770.

A. Submitter

Linvatec Corporation
11311 Concept Boulevard
Largo, Florida 33773-4908

B. Company Contact

Laura Seneff
Manager, Regulatory Affairs

C. Device Name

Trade Name: : BioRC Anchor

Common Name : BioAbsorbable Soft Tissue Anchor

Classification Names : None Assigned

Proposed Class/Device Product Code : Class II-87 MAI, Fastener Fixation, Biodegradable, Soft Tissue

D. Predicate/Legally Marketed Devices

Revo Suture Anchor
Linvatec Corporation

Suretac
Acufex

Pre-loaded Bio-Anchor
Linvatec Corporation

E. Device Description

The BioRC Anchor is a cannulated, threaded, sterile, single-use fixation device made from a bioabsorbable homopolymer, Poly(L-lactide acid), which is used to attach soft tissue to bone. The device is preloaded on a disposable driver used to insert it into the bone.

F. Intended Use

This device is used to attach soft tissue to bone in arthroscopic or open procedures for the following indications:

Shoulder

1. Bankart lesion repair
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. Lateral and Medial Epicondylitis
4. Biceps tendon reattachment

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 BioRC Anchor is substantially equivalent in design and intended use to the Revo Suture Anchor (Linvatec Corporation) and SureTac (Acufex).

The BioRC Anchor is substantially equivalent in materials to the Pre-loaded Bio-Anchor Absorbable Suture Anchor (Linvatec Corporation).

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

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

CHART OF SIMILARITIES AND DISSIMILARITIES

Company	Device Name	Intended Use	Material	Single-Use Reusable	Method of Sterilization	Design
NEW PRODUCT Linvatec Corp.	BioRC Anchor	Soft tissue to bone fixation for shoulder, knee, foot, ankle, elbow, wrist, hand and bladder neck suspension procedures.	Poly(L-lactic acid)	Sterile Single-use	Ethylene Oxide	6mm x 22mm Threaded, cannulated device with a head to attach soft tissue to bone.
PREDICATE Linvatec Corp. 510(K)# K963932	Revo Suture Anchor	Soft tissue to bone fixation for shoulder, knee, foot, ankle, elbow, wrist, hand and bladder neck suspension procedures.	Titanium Alloy	Sterile Single-use	Gamma Radiation	2.5mm-5.2mm length Threaded device that attaches soft tissue to bone.
PREDICATE Acufex 510(K)# K911837	Suretac	Soft tissue to bone fixation.	Polyglyconate	Sterile Single-use	Ethylene Oxide	8mm x 16mm Cannulated tack with ribs to hold the device in the bone.
PREDICATE Linvatec Corp 510(K)# K983186	Pre-loaded Bio-Anchor	Soft tissue to bone fixation for shoulder, knee, foot, ankle, elbow, wrist, hand and bladder neck suspension procedures.	Poly(L-lactic acid)	Sterile Single-use	Ethylene Oxide	3.5mm x 10.5mm Ribbed device with a loop at the proximal end to hold suture which attaches the soft tissue.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 30 1999

Ms. Laura Seneff
Manager, Regulatory Affairs
Linvatec Corporation
11311 Concept Boulevard
Largo, Florida 33773-4908

Re: K990770
Trade Name: BioRC Anchor
Regulatory Class: II
Product Code: MAI, HWC
Dated: May 13, 1999
Received: May 14, 1999

Dear Ms. Seneff:

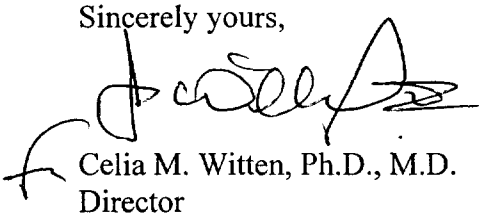
We have reviewed your Section 510(k) notification of intent to market the device referenced above, and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 control provisions of the Act. The general control 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): K990770

Device Name: BioRC Anchor

Indications for Use:

The BioRC Anchor is a bioabsorbable device used to attach soft tissue to bone in arthroscopic or open procedures for the following indications:

Shoulder
1. Bankart lesion repair
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. Lateral and Medial Epicondylitis
4. Biceps tendon reattachment

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

Prescription Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K9907

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)

Prescription Use X OR Over-the-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K940770