

K991024

NOV 16 1999

September 15, 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 **Bone Bullet Suture Anchor**, 510(k) Number K991024.

A. Submitter

Linvatec Corporation
11311 Concept Boulevard
Largo, Florida 33773-4908

B. Company Contact

Laura Seneff
Manager, Regulatory Affairs

C. Device Name

Trade Name: : **Bone Bullet Suture Anchor**

Common Name : **Suture Anchor**

Classification Names : **Smooth or threaded
metallic bone fixation
fastener 21 CFR 888.3040**

Proposed Class/Device : **Class II-78 MBI**
Product Code

D. Predicate/Legally Marketed Devices

Mini-Revo Soft Tissue Anchor
Linvatec Corporation

UltraFix MicroMite
Li Medical

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E. Device Description

The Bone Bullet Suture Anchor is a titanium suture anchoring device with an attached coated non-absorbable braided suture size SP #2-0 used to attach soft tissue to bone.

F. Intended Use

This device is used to attach soft tissue to bone for the following indications:

Foot and Ankle

1. Hallux Valgus repairs
2. Midfoot reconstructions

Elbow, Wrist and Hand

1. Scapholunate ligament reconstructions
2. Ulnar or radial collateral ligament reconstructions
3. PIP joint ligament reconstructions
4. Profundus tendon reattachment

G. Substantial Equivalence

The Bone Bullet Suture Anchor is substantially equivalent in function and intended use to the Mini-Revo Suture Anchor (Linvatec Corporation) and UltraFix MicroMite (Li Medical).

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

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Bone Bullet Suture Anchor

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CHART OF SIMILARITIES AND DISSIMILARITIES

Company	Device Name	Intended Use	Material	Single-Use Reusable	Method of Sterilization	Design
NEW PRODUCT Linvatec Corp.	Bone Bullet	Soft tissue to bone fixation for foot, ankle, elbow, wrist and hand surgical procedures.	Titanium Alloy	Sterile Single-use	Gamma Radiation	Length 4.57mm Diameter 1.3mm
PREDICATE Linvatec Corp. 510(k)# K953954	Mini-Revo Suture Anchor	Soft tissue to bone fixation for shoulder, knee, foot, ankle, elbow, wrist and hand surgical procedures.	Titanium Alloy	Sterile Single-use	Gamma Radiation	Length 8.89mm Diameter: 2.8mm (Major) 1.6mm (Minor)
PREDICATE Li Medical 510(k)# K981764	UltraFix MicroMite	Soft tissue to bone fixation for shoulder, wrist, elbow, knee, foot and ankle surgical procedures.	Titanium Alloy	Sterile Single-use	Gamma Radiation	Length 3.7mm Diameter: 1.3mm (undeployed) 2.7mm (deployed)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NOV 16 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K991024
Trade Name: Bone Bullet™ Suture Anchor
Regulatory Class: II
Product Codes: HWC and MBI
Dated: September 16, 1999
Received: September 20, 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 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.

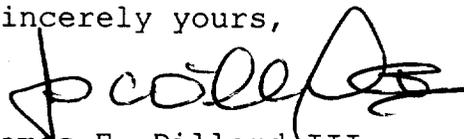
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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,



James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number K991024

Device Name: **Bone Bullet™ Suture Anchor**

Indications for Use:

The Bone Bullet Suture Anchor is used to attach soft tissue to bone for the following indications:

Foot and Ankle

- 1. Hallux Valgus repairs
- 2. Midfoot reconstructions

Elbow, Wrist and Hand

- 1. Scapholunate ligament reconstructions
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- 3. PIP joint ligament reconstructions
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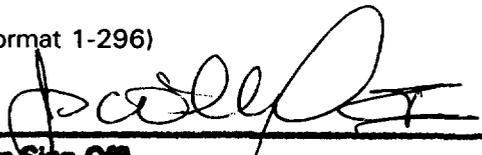
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-296)



 (Division Sign-Off)
 Division of General Restorative Devices
 510(k) Number K991024