K043106 page 1 of 3

JAN 19 2005

PROPRIETARY INFORMATION – LINVATEC CORPORATION

November 5, 2004

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 Traditional 510(k) Summary of Safety and Effectiveness for the Pinn –ACL CrossPin 510(k) Number _____.

A. Submitter

Linvatec Corporation
11311 Concept Boulevard
Largo, Florida 33773-4908
Registration Number: 1017294

B. Company Contact

Elizabeth M. Paul
Manager, Regulatory Affairs
(727) 399-5234 Telephone
(727) 399-5264 FAX

C. Device Name

Trade Name: Pinn-ACL® CrossPin

Common Name: crosspin

Classification Names: Fastener, Fixation, Biodegradable, Soft Tissue, 21 CFR 888.3030

Proposed Class/Device: Class II

Product Code: MAI

Summary of Safety and Effectiveness
Pinn-ACL® Crosspin
510(k) # _____
November 5, 2004

D. Predicate/Legally Marketed Devices

Bio – Transfix Arthrex, Inc.	510(k) # K011172
Rigid Fix® Mitek	510(k) # K974341
Bionx SmartScrew ® Bionx	510 (k) # 003077
BioScrew® Linvatec Corporation	510(k) # K973758

E. Device Description

The Linvatec Pinn-ACL® CrossPin consists of absorbable crosspin and graft harness implants made from poly L-lactic acid, high strength polyethylene fiber to be used with manual, re-useable instruments to facilitate the precise positioning of the implants (Crosspin refers to the both the crosspin and graft harness implants. The implants are single-use and sterile. The instruments are supplied non-sterile and must be sterilized prior to use.

F. Intended Use

The Pinn–ACL® CrossPin is intended to provide femoral fixation of soft tissue grafts for reconstruction of cruciate ligaments in the knee.

G. Substantial Equivalence

The Pinn-ACL® CrossPin is substantially equivalent to in design and intended use and materials to the Bio – Transfix (510(k) # K011172) and Arthrex, Inc., RigidFix™ (510(k) # K974341).

The Pinn-ACL® CrossPin implant is identical to the materials in the SmartScrew® (510(k) # K003077) and the BioScrew ®(510(k) # K097358).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 19 2005

Ms. Elizabeth M. Paul
Manager, Regulatory Affairs
Linvatec Corporation
11311 Concept Boulevard
Largo, Florida 33773

Re: K043106
Trade/Device Name: Pinn-ACL® CrossPin
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HTY
Dated: November 5, 2004
Received: November 9, 2004

Dear Ms. Paul:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

November 5, 2004

510(k) Number (if known): K043106

Device Name: Pinn –ACL® CrossPin

Indications for Use:

The Pinn – ACL® CrossPin is intended to provide femoral fixation of soft tissue grafts for reconstruction of cruciate ligaments in the knee.

Prescription Use __X____ AND/OR Over-The-Counter Use No

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K043106