MAR 2 5 2005

PROPRIETARY INFORMATION – LINVATEC CORPORATION

February 8, 2005

510(k) Submission

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 a Special 510(k) Summary of Safety and Effectiveness for BioScrew® XtraLok® 8 x 35mm-Violet and BioScrew® XtraLok® 8 x 40mm-Violet, 510(k) Number K050497

A. Submitter

Linvatec Corporation
11311 Concept Boulevard
Largo, Florida 33773-4908

B. Company Contact

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

C. Device Name

Trade Name: BioScrew® XtraLok® 8 x 35mm-Violet and
BioScrew® XtraLok® 8 x 40mm-Violet

Common Name: Bioabsorbable Interference Screw

Classification Names: Fastener, Fixation, Biodegradable, Soft Tissue

Proposed Class/Device: Class II
Product Code HWC

PROPRIETARY INFORMATION – LINVATEC CORPORATION

February 8, 2005
510(k) Submission
BioScrew® XtraLok® 8 x 35mm and 8 x 40mm,violet
510(k) # _____

D. Predicate/Legally Marketed Devices

BioScrew® XtraLok™ 510(k)# K013131
Linvatec Corporation

E. Device Description

The BioScrew® XtraLok® 8 x 35mm and 8 x 40mm, violet are cannulated, sterile, single-use bone screws made of an absorbable homopolymer derived from Poly (L-Lactic Acid).

Two sizes will be available for the device, 8 x 35mm and 8 x 40mm. The BioScrew® XtraLok® 8 x 35mm and 8 x 40mm, violet, differ from the existing Linvatec BioScrew® XtraLok™ in that the major diameter is smaller. The violet colorant contained in this device, has been cleared for this product code and intended use by the FDA via color petition 8C0255 dated January 28, 1998.

The modification does not affect the device's intended use, fundamental scientific technology or performance specifications.

F. Intended Use

The BioScrew® XtraLok® 8 x 35mm and 8 x 40mm,violet, provide tibial interference fixation of a soft tissue graft for ACL and PCL reconstruction.

G. Substantial Equivalence

The BioScrew® XtraLok® 8 x 35mm and 8 x 40mm, violet, are substantially equivalent in design, materials and intended use to the BioScrew® XtraLok™. The BioScrew® XtraLok® 8 x 35mm and 8 x 40mm, violet, do not raise any new issues of safety or effectiveness when compared to this predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 25 2005

Ms. Elizabeth Paul
Manager, Regulatory Affairs
Linvatec Corp.
11311 Concept Boulevard.
Largo, Florida 33773-4908

Re: K050497
Trade/Device Name: Bioscrew® XtraLok™
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: February 15, 2005
Received: February 28, 2005

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

Miriam Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050497

Device Name:
BioScrew® XtraLok® 8 x 35mm-Violet and
BioScrew® XtraLok® 8 x 40mm-Violet

Indications for Use:
The BioScrew® XtraLok® 8 x 35mm and 8 x 40mm, violet provide tibial interference fixation of a soft tissue graft for ACL and PCL reconstruction.

Prescription Use X OR Over-the-Counter Use No
(Part 21 CFR 801 subpart D) (Part 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)

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

510(k) Number K050497