NOV - 4 2004



October 1, 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 Special 510(k) Summary of Safety and Effectiveness for the BioAnchor® with Disposable Driver, Preloaded with One #2 Herculine™ Suture 510(k) Number K042778

### A. Submitter

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

### B. Company Contact

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

### C. Device Name

| | |
|---|---|
| Trade Name: | BioAnchor® with Disposable Driver, Preloaded with One #2 Herculine™ Suture |
| Common Name: | Suture Anchor |
| Classification Names: | Screw, Fastener Fixation, Biodegradable, Soft tissue; 21 CFR 888.3040. Suture, Nonabsorbable, Synthetic, Polyethylene; 21 CFR 878.5000 |
| Proposed Class/Device: | Class II |
| Product Code: | MAI, GAT, HWC |

**PROPRIETARY INFORMATION – LINVATEC CORPORATION**

Summary of Safety and Effectiveness
BioAnchor® with Disposable Driver, Preloaded with One #2 Herculine™ Suture
510(k) # K042778
October 1, 2004

## D. Predicate/Legally Marketed Devices

BioAnchor® with Disposable Driver — 510(k) # K033804
Linvatec Corporation

## E. Device Description

The BioAnchor® with Disposable Driver, Preloaded with One #2 Herculine™ Suture is an injection molded Poly (L-lactic) –PLLA suture anchor implant pre-threaded with a single strand of #2 non-absorbable Herculine braided polyethylene suture, preloaded onto a disposable driver with a stainless steel shaft and ABS handle. The BioAnchor® with Disposable Driver, Preloaded with One #2 Herculine™ Suture is supplied sterile and single use.

The modification described in this Special 510(K) is to replace the USP #2 polyester non-absorbable suture with a Herculine™ High Strength polyethylene non-absorbable suture.

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

## F. Intended Use

The BioAnchor® with Disposable Driver, Preloaded with One #2 Herculine™ Suture is intended for soft tissue repair of the shoulder; specifically, Bankhart and SLAP repair, capsular shifts and capsulolabral reconstruction.

## G. Substantial Equivalence

The BioAnchor® with Disposable Driver, Preloaded with One #2 Herculine™ Suture is substantially equivalent in design and intended use to the BioAnchor® with Disposable Driver. Testing has been conducted to assure that changing the suture in the device does not raise any new issues regarding safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 4 2004

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

Re: K042778
Trade/Device Name: BioAnchor® with Disposable Drive, Preloaded with #2 Herculine™ Suture
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC, MAI
Dated: October 1, 2004
Received: October 6, 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/dsma/dsmamain.html

Sincerely yours,

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

PROPRIETARY INFORMATION – LINVATEC CORPORATION

# Indications for Use

510(k) Number (if known): K042778

Device Name: BioAnchor® with Disposable Driver, Preloaded with One #2 Herculine™ Suture

Indications For Use:

The BioAnchor® with Disposable Driver, Preloaded with One #2 Herculine™ Suture is intended for soft tissue repair of the shoulder; specifically, Bankhart and SLAP repair, capsular shifts and capsulolabral reconstruction.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __No__ (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 Mark N Milhern

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

510(k) Number K042778 Page 1 of 1