K050227

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[redacted] LINVATEC CORPORATION

February 07, 2005

510(k) SUMMARY

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 ThRevo™ Suture Anchor with Disposable Driver 510(k) Number _____.

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:	ThRevo™ Suture Anchor with Disposable Driver
Common Name:	Suture Anchor
Classification Names:	Screw, Fastener, Fixation, Nondegradable, Soft Tissue, 21 CFR 888.3040
Proposed Class/Device:	Class II
Product Code:	MBI

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[redacted] LINVATEC CORPORATION

510(k) Summary (Continued)
ThRevo™ Suture Anchor with Disposable Driver
510(k) # _____
February 07, 2005

D. Predicate/Legally Marketed Devices

Super Revo® Suture Anchor 510(k) # K003984
Linvatec Corporation

E. Device Description

The ThRevo™ Suture Anchor with Disposable Driver consists of a titanium suture anchor with a self-tapping cutting tip. The design requires no predrilling and can be inserted by hand into the bone with the accompanying disposable driver. The ThRevo™ Suture Anchor with Disposable Driver is substantially equivalent in design, performance specifications, function and intended use to the Super Revo® Suture Anchor. The design of the implant has not been modified.

The only modification to the currently marketed device is the ThRevo™ Suture Anchor with Disposable Driver is preloaded with three (3) nonabsorbable USP size # 2 braided polyester sutures (green, white and green/white striped) instead of two (2) nonabsorbable, USP size # 2 braided polyester sutures (green and white). The surgical technique has been slightly modified to for account for the addition of the third suture.

The implant design has not been modified in any way. The titanium suture anchor implant of the ThRevo™ Suture Anchor with Disposable Driver is the same as for the Super Revo® Suture Anchor (510(k) # K003984). Both are provided preloaded onto a disposable driver with a stainless steel shaft and ABS handle. Also, both the ThRevo™ Suture Anchor with Disposable Driver and Super Revo® Suture Anchor are supplied sterile and single use.

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

F. Intended Use

The ThRevo™ Suture Anchor with Disposable Driver is intended to be used for rotator cuff repairs in the shoulder either arthroscopically or in a mini-open technique.

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[redacted] – LINVATEC CORPORATION

510(k) Summary (Continued)
ThRevo™ Suture Anchor with Disposable Driver
510(k) # _____
February 07, 2005

G. Substantial Equivalence

The ThRevo™ Suture Anchor with Disposable Driver is substantially equivalent in intended use, scientific technology and design to the Super Revo® Suture Anchor. Testing has been conducted to assure that providing the suture anchor with the additional strand of nonabsorbable USP #2 polyester suture does not raise any new issues regarding safety and effectiveness.

Surgical Specialties, Redding, Pennsylvania, supplies two (2) non-absorbable USP #2 Silicone coated polyester braided sutures (Polyviolene), which are approved under NDA 80-950

TeleFlex Medical, Coventry, Connecticut, supplies the additional third non-absorbable USP #2 PTFE coated polyester braided suture (Polydek) which is approved for commercial distribution in the U.S. under 510(k) number K021019.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 - 2005

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

Re: K050227
Trade/Device Name: ThRevo™ Suture Anchor with Disposable Driver
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: MBI
Dated: January 24, 2005
Received: February 1, 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) 276-0115. 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 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,

Miriam C Provost

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

January 10, 2005

510(k) Number (if known): K050227

Device Name: ThRevo™ Suture Anchor with Disposable Driver

Indications for Use: The ThRevo™ Suture Anchor with Disposable Driver is intended to be used for rotator cuff repairs in the shoulder either arthroscopically or in a mini-open technique.

Prescription Use_X__ OR Over-the-Counter Use
(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 1-2-96)

Miriam C. Provost

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

510(k) Number K050227