4/29/99

Linvatec

11311 Concept Boulevard Largo, Florida 33773-4908 727 392-6464

K984171

February 9, 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 EndoPearl, 510(k) Number K984171.

A. Submitter

Linvatec Corporation
11311 Concept Boulevard
Largo, Florida 33773-4908

B. Company Contact

Laura Seneff
Manager, Regulatory Affairs

C. Device Name

Trade Name:	:	EndoPearl
Common Name	:	EndoPearl
Classification Names	:	None Assigned
Proposed Class/Device Product Code	:	Class II-87 MAI, Fastener Fixation, Biodegradable, Soft Tissue

D. Predicate/Legally Marketed Devices

EndoButton
Acufex Microsurgical Inc.

E. Device Description

The EndoPearl BioAbsorbable Soft Tissue Device is a cannulated, sterile, single-use fixation device made from a bioabsorbable homopolymer, Poly (L-lactic acid) that will gradually be metabolized by the body.

F. Intended Use

This device is used in conjunction with the Linvatec BioScrew® bioabsorbable interference screw, as a back-up to interference screw fixation of soft tissue grafts on the femoral side of an ACL/PCL reconstruction.

G. Substantial Equivalence

The EndoPearl is substantially equivalent in function and intended use to the EndoButton (Acufex Microsurgical Inc.).

Testing has been done to prove safety and effectiveness of the device.

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

CHART OF SIMILARITIES AND DISSIMILARITIES

Company	Device Name	Intended Use	Material	Single-Use Reusable Method of Sterilization	Design
NEW PRODUCT Linvatec	EndoPearl BioAbsorbable Soft Tissue Device	Used in conjunction with Linvatec's BioScrew® bioabsorbable interference screw, as a back-up to interference screw fixation of soft tissue grafts on the femoral side of an ACL/PCL reconstruction.	Poly (L-lactic acid)	Single-Use ETO	7mm, 8mm, 9mm sizes Design is a sphere with a 2mm central hole.
PREDICATE Acufex Microsurgical Inc. 510(K)# K922559	EndoButton	Suture fixation in the repair of tendons and ligaments.	Titanium Alloy	Single Use Gamma Radiation Sterilization	Sizes :4mm x 12mm 4mm x 16.5mm Design is a flat rectangular plate with four holes going across.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 29 1999

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

Re: K984171
Trade Name: EndoPearl
Regulatory Class: II
Product Codes: MAI and HWC
Dated: February 9, 1999
Received: February 10, 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.

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,

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

Enclosure

February 9, 1999 Page 1 of 1

510(k) Number (if known): K984171

Device Name: EndoPearl

Indications for Use:

The EndoPearl is used in conjunction with the Linvatec BioSc bioabsorbable interference screw, as a back-up to interferer screw fixation of soft tissue grafts on the femoral side of ACL/PCL reconstruction.

(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 Devices
510(k) Number K9

Prescription Use Yes OR Over-the-Counter Use No

(Per 21 CFR 801.109)