

DEC 10 1999

K993339

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October 4, 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™ With Threader, 510(k) Number _____.

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

D. Predicate/Legally Marketed Devices

EndoPearl™
Linvatec Corporation

Summary of Safety and Effectiveness

EndoPearl™ With Threader

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E. Device Description

The EndoPearl™ With Threader 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.

The EndoPearl™ comes preloaded on a suture threader (with nitinol wire) to facilitate the threading of the suture into the EndoPearl™ during graft preparation by the surgeon, resident, PA, or nurse.

F. Intended Use

This device is used in conjunction with a 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™ With Threader is substantially equivalent in function and intended use to the EndoPearl™ (Linvatec Corporation).

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

Summary of Safety and Effectiveness
 EndoPearl™ With Threader
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CHART OF SIMILARITIES AND DISSIMILARITIES

Company	Device Name	Intended Use	Material	Single-Use Reusable Method of Sterilization	Design
NEW PRODUCT Linvatec	EndoPearl™ With Threader Bioabsorbable Soft Tissue Device	Used in conjunction with a 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.	EndoPearl: Poly (L-lactic acid) Threader: Ultem with Nitinol Wire	Single-Use ETO	7mm, 8mm, 9mm
PREDICATE Linvatec EndoPearl™ 510(K) # K984171	EndoPearl™	Used in conjunction with a 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.	Poly (L-lactic acid)	Single-Use ETO	7mm, 8mm, 9mm



DEC 10 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K993339

Trade Name: EndoPearl™ With Threader
Regulatory Class: II
Product Code: MAI and HWC
Dated: October 4, 1999
Received: October 5, 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.

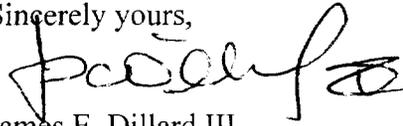
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 – Ms. Laura Seneff

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 at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "James E. Dillard III". The signature is fluid and cursive, with a large initial "J" and "D".

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

October 4, 1999

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510(k) Number (if known): K993339

Device Name: EndoPearl™ With Threader

Indications for Use:

The EndoPearl™ With Threader is used in conjunction with a 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.

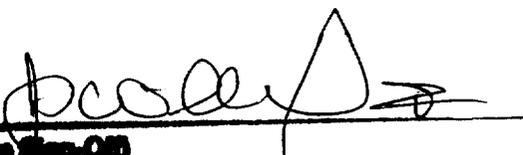
(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ Concurrence of CDRH, Office of Device Evaluation (ODE) _____

Prescription Use X OR Over-the-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-296)



(Division Sign-Off)
Division of General Restorative Devices K993339
510(k) Number _____