

AUG -6

May 19, 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 BioStinger™-V Bioabsorbable Meniscal Repair Device.

A. Submitter

Linvatec Corporation
11311 Concept Boulevard
Largo, Florida 33773

B. Company Contact

Laura Seneff
Manager, Regulatory Affairs

C. Device Name

Trade Name:	BioStinger™-V Bioabsorbable Meniscal Repair Device
Common Name:	Meniscal Repair Device
Classification Name/ Reference:	None Assigned
Proposed Class/ Device Product Code:	Class II-87 MAI, Fastener, Fixation, Biodegradable, Soft Tissue

D. Predicate/Legally Marketed Devices

Linvatec Meniscal Repair Device

E. Device Description

The BioStinger™-V Bioabsorbable Meniscal Repair Device is a cannulated, sterile, single-use fixation device made of an absorbable homopolymer derived from poly(L-lactic acid), similar to that used in bioabsorbable suture and will gradually be absorbed into the body. The device is colored with D&C Violet #2.

Summary of Safety and Effectiveness
BioStinger™-V Bioabsorbable Meniscal Repair Device
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F. Intended Use

The BioStinger™-V Bioabsorbable Meniscal Repair Device provides fixation of longitudinal vertical meniscus lesions (bucket-handle) located in the vascularized area of the meniscus.

Implantation of the fixation device is accomplished through arthroscopy or arthrotomy.

G. Substantial Equivalence

The colored BioStinger™-V Bioabsorbable Meniscal Repair Device is substantially equivalent in design, function and intended use to the Linvatec BioStinger™ Bioabsorbable Meniscal Repair Device.

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

CHART OF SIMILARITIES AND DISSIMILARITIES

Company Name	Device Name	Intended Use	Material	Single-Use Reusable	Method of Sterilization	Design
New Product Linvatec	BioStinger™-V Bioabsorbable Meniscal Repair Device	Fixation of longitudinal vertical meniscus lesions (bucket handle) located in the vascularized area of the meniscus.	Poly(L-lactic acid) with color additive D&C Violet #2	Sterile Single-use	EtO 16-month shelf life	Cannulated Barbed tack with head Sizes: 1.3mm diameter x 10mm-16mm length
Predicate Linvatec Corporation 510(k) #K981692	Linvatec Meniscal Repair Device	Fixation of longitudinal vertical meniscus lesions (bucket handle) located in the vascularized area of the meniscus.	Poly(L-lactic acid)	Sterile Single-use	EtO 16-month shelf life	Cannulated Barbed tack with head Sizes: 1.3mm diameter x 10mm-16mm length



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG -6 1999

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

Re: K991715
Biostinger-V Bioabsorbable Meniscal Repair Device
Regulatory Class: II
Product Code: MAI, HTY
Dated: May 19, 1999
Received: May 20, 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 control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

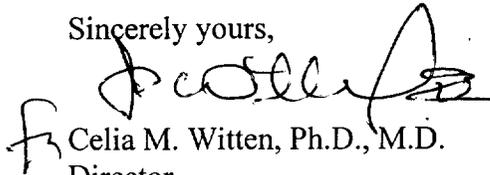
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

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 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 'C. Witten', is written over the typed name.

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

Date: May 19, 1999

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510(k) Number (if known): K 991715

Device Name: BioStinger™-V Bioabsorbable Meniscal Repair Device

Indications for Use:

The BioStinger™-V Bioabsorbable Meniscal Repair Device provides fixation of longitudinal vertical meniscus lesions (bucket-handle) located in the vascularized area of the meniscus.

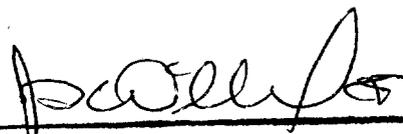
Implantation of the device is accomplished through arthroscopy or arthrotomy.

(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)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K 991715