SEP 17 1999 K990194

September 2, 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 **BioButton™ - Recessed Ligament Button**, 510(k) Number K990194.

A. Submitter

Linvatec Corporation
11311 Concept Boulevard
Largo, Florida 33773-4908

B. Company Contact

Laura Seneff
Manager, Regulatory Affairs

C. Device Name

Trade Name:	:	**BioButton™**
Common Name	:	**Recessed Ligament Button**
Classification Names	:	**Smooth or threaded metallic bone fixation fastener 888.3040**
Proposed Class/Device Product Code	:	**Class II-87 HWC**

D. Predicate/Legally Marketed Devices

BioScrew® Absorbable Interference Screw
Linvatec Corporation

Hewson Ligament Guide and Button
Richards Manufacturing Company, Inc.

E. Device Description

The BioButton™ is a sterile, single-use fixation device made from an absorbable homopolymer derived from Poly (L-lactic) Acid that will gradually be metabolized by the body. The implant is attached to a soft tissue or bone-tendon-bone autograph or allograft during anterior and posterior cruciate ligament reconstruction. The implant is radiotranslucent with regard to intraoperative fluoroscopy, but it can be visualized with MRI and CAT scan.

F. Intended Use

The BioButton is a cortical fixation device used for secondary fixation in conjunction with an interference screw to secure soft tissue or bone-tendon-bone grafts in ACL and PCL reconstruction.

G. Substantial Equivalence

The BioButton™ is substantially equivalent in function and intended use to the Hewson Ligament Button, Richards Manufacturing Co., Inc.

The BioButton is substantially equivalent in materials used to the BioScrew® Absorbable Interference Screw (Linvatec Corporation) - 510(K)# K973758.

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

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 17 1999

Ms. Laura D. Seneff
Manager, Regulatory Affairs
Linvatec Corporation
11311 Concept Blvd
Largo, Florida 33773

Re: K990194
Trade Name: BioButton™ Recessed Ligament Button
Regulatory Class: II
Product Code: HWC
Dated: June 22, 1999
Received: June 23, 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 at (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

510(k) Number: K990194

Device Name: **BioButton™ - Recessed Ligament Button**

Indications for Use:

The BioButton™ is a cortical fixation device used for secondary fixation in conjunction with an interference screw to secure soft tissue or bone-tendon-bone grafts in ACL and 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)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990194

(Optional Format 1-296)