3/23/99

Linvatec

11311 Concept Boulevard Largo, Florida 33773 727 399-5334 Fax 727 399-5264

Carol A. Weideman, Ph.D.
Director
Compliance and Regulatory Affairs

October 16, 1998

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 Ablator Electrode, 510(k) Number K983652

A. Submitter

Linvatec Corporation
11311 Concept Boulevard
Largo, Florida 33773-4908

B. Company Contact

Carol A. Weideman, Ph.D.
Director, Compliance and Regulatory Affairs

C. Device Name

Trade Name:	:	Ablator Electrode
Common Name	:	Electrode
Classification Names	:	Electrosurgical cutting and coagulation device and accessories, 878.4400
Proposed Class/Device Product Code	:	Class II, 79 JOS, Electrode, Electrosurgical

D. Predicate/Legally Marketed Devices

ESA Electrodes
Linvatec Corporation

ArthroCare® Electrosurgery System 2000
ArthroCare Corporation

VAPR™
Mitek Products

E. Device Description

The Ablator Electrode is packaged in a kit containing an Ablator Electrode, electrosurgical pencil, and a electrosurgical dispersive pad. The electrode will also be sold individually. The electrode is connected to an electrosurgical generator via the electrosurgical pencil.

F. Intended Use

The Ablator Electrode is designed for general surgical use, including orthopaedic and arthroscopic applications of resection, ablation, excision of soft tissue, hemostasis of blood vessels and in coagulating soft tissues. Arthroscopic surgery includes the following:

Knee

1. Meniscectomy
2. Lateral Release
3. Chondroplasty
4. Synovectomy
5. ACL Debridement
6. Plica Removal
7. Meniscal Cystectomy

Ankle

1. Fracture Debridement
2. Excision of Scar Tissue
3. Synovectomy
4. Chondroplasty

Wrist

1. Synovectomy
2. Cartiledge Debridement
3. Fracture Debridement

Intended Use (cont.)

Shoulder

1. Labral Tear Resection
2. Synovectomy
3. Excision of Scar Tissue
4. Acromioplasty
5. Bursectomy
6. Subacromial Decompression
7. Chondroplasty

Elbow

1. Synovectomy
2. Tendon Debridement
3. Chondroplasty

G. Substantial Equivalence

The Ablator Electrode is substantially equivalent in design, function and intended use to the ESA Electrodes (Linvatec Corporation), ArthroCare® Electrosurgery System 2000 (ArthroCare Corporation), and VAPR™ (Mitek Products)

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

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 23 1999

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

Re: K983652
Trade Name: Ablator Electrode
Regulatory Class: II
Product Code: HRX and GEI
Dated: February 16, 1999
Received: February 17, 1999

Dear Ms. Seneff:

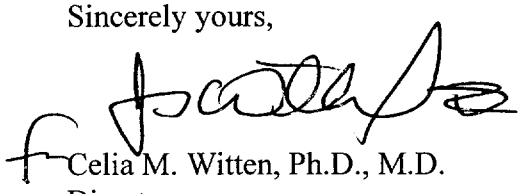
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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) 594-4595. 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

3/23/99

Linvatec

11311 Concept Boulevard Largo, Florida 33773-4908 813 392-6464

October 16, 1998

510(k) Number (if known): K983652

Device Name: Ablator Electrode

Indications for Use:

The Ablator Electrode is designed for general surgical use, including orthopaedic and arthroscopic applications of resection, ablation, excision of soft tissue, hemostasis of blood vessels and in coagulating soft tissues. Arthroscopic surgery includes the following:

Knee

1. Meniscectomy
2. Lateral Release
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Ankle

1. Fracture Debridement
2. Excision of scar tissue
3. Synovectomy
4. Chondroplasty

Wrist

1. Synovectomy
2. Cartilage Debridement
3. Fracture Debridement

Shoulder

1. Labral Tear Resection
2. Synovectomy
3. Excision of Scar Tissue
4. Acromioplasty
5. Bursectomy
6. Subacromial Decompression
7. Chondroplasty

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983652

Prescription Use X
(Per 21 CFR 801.109)

Intended Use (cont.)

Elbow

1. Synovectomy
2. Tendon Debridement
3. Chondroplasty

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use_____

(Per 21 CFR 801.109)

(Optional Format 1-296)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983652