Linvatec

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

JUN - 3 2003

March 6, 2003

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 UltrAblator Electrode 510(k) Number K030720

A. Submitter

Linvatec Corporation
11311 Concept Boulevard
Largo, Florida 33773-4908

B. Company Contact

Laura D. Seneff, RAC
Manager, Regulatory Affairs
(727) 399-5234 Telephone
(727) 399-5264 FAX

C. Device Name

Trade Name: UltrAblator Electrode

Common Name: Electrode

Classification Names: Electrosurgical cutting and coagulation device and accessories, 878.4400

Proposed Class/Device: Class II
Product Code: JOS & GEI

II

D. Predicate/Legally Marketed Devices

UltrAblator Electrode	K993885
Linvatec Corporation	

E. Device Description

The UltrAblator Electrode is a sterile, single-use monopolar electrode that is connected to an electrosurgical generator via an electrosurgical pencil.

The modification to the UltrAblator Electrode described in this 510(k) is a change to the insulation material.

This modification does not affect the indications for use, operational instructions, performance specifications or labeling.

F. Intended Use

The UltrAblator Electrode is intended to be used in arthroscopic applications of resection, ablation, tissue modification, excision of soft tissue, hemostasis of blood vessels and in coagulating soft tissues. Areas of application include knee, shoulder, ankle, wrist and elbow arthroscopic procedures.

G. Substantial Equivalence

The UltrAblator Electrode is substantially equivalent in design, technology and intended use to Linvatec's existing UltrAblator Electrode. Performance testing has been conducted to show that the new design does not raise any new issues regarding safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 3 2003

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

Re: K030720
Trade/Device Name: UltrAblator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI, JOS
Dated: May 9, 2003
Received: May 13, 2003

Dear Ms. Seneff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), 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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

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

Enclosure

March 6, 2003

510(k) Number (if known): K030720

Device Name: UltrAblator Electrode

Indications for Use:

The UltrAblator Electrode is intended to be used in arthroscopic applications of resection, ablation, tissue modification, excision of soft tissue, hemostasis of blood vessels and in coagulating soft tissues. Areas of application include knee, shoulder, ankle, wrist and elbow arthroscopic procedures.

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030720

(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 1-2-96)