K993885

FEB 1 0 2000

Summary

The following information is supplied in accordance with Public Law 94-295, "Medical Device Amendment", Section 510(k) requiring premarket notification.

Linvatec manufactures all its products and maintains such records as it considers necessary to satisfy the known requirements of the Act. Linvatec Corporation, hereby notifies the Food and Drug Administration of its intent to market the following:

1. Manufacturer Identification:

Linvatec Corporation
11311 Concept Boulevard
Largo, FL 33773-4908
Registration No. 1017294

Contact Person: Laura Seneff, RAC
Manager, Regulatory Affairs
Phone Number: 727-399-5234
Fax Number: 727-399-5264

2. Device Identification:

Proprietary Name: UltrAblator™ Electrode

Common Name: Electrode

Classification Name/Reference: Electrosurgical cutting and coagulation device and accessories, 878.4400

Proposed Class/ Device Product Code: Class II, 79 JOS, Electrode, Electrosurgical

3. 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. Arthroscopic surgery includes the following:

Knee

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

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Intended Use (Continued)

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

Elbow

1. Synovectomy
2. Tendon Debridement
3. Chondroplasty

4. Device Description:

The UltrAblator™ Electrode is a monopolar electrode which will be packaged individually or in a kit containing an UltrAblator™ Electrode, ConMed electrosurgical pencil, and a ConMed electrosurgical dispersive pad. The electrode is connected to an electrosurgical generator via the ConMed electrosurgical pencil. The device is inserted into the joint. Upon activation of the generator, the tip of the device electrosurgically ablates and coagulates tissue.

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The UltrAblator™ Electrode is a modification of Linvatec's Ablator Electrode which received FDA clearance under 510(k)# K983652 on March 23, 1999. The electrode will be made available in a range of sizes from 2.4" to 6.3" inches in working length, and in three angles, 0°, 30°, & 90°. The insulating material will be changed from polyolefin shrink to Vitek powder coat.

ConMed's electrosurgical dispersive pad has received clearance for marketing under 510(K) Number K791137. ConMed's electrosurgical pencil has received clearance to market the device under 510(K) Number K954633.

Linvatec is a wholly owned subsidiary of ConMed Corporation.

Advertisement and labeling are included in Exhibit 1.

Pictures of the device are included in Exhibit 2.

Engineering drawings are included in Exhibit 3.

5. Materials:

Tip/Shaft:	304 Stainless Steel, ASTM A-908
Shrink Tube:	Vitek Coating, No ASTM Reference
Insulator:	Zirconia or Alumina, No ASTM Reference
Hub:	Nylon, ASTM GFN2

6. Labeling:

Proposed labeling is included in Exhibit 1.

7. Additional Information:

Engineering testing will be performed per ANSI/AAMI American National Standard for Electrosurgical Devices HF-18/1993. Test protocols are included in Exhibit 4 for the following tests: 3,000 VAC Dielectric Withstand Test; 1.5 Times Maximum Voltage Withstand Test; 18 Minute Run Test, and Resection Effectiveness Test.

Biocompatibility testing was performed on the final packaged sterilized device per ISO Standard 10993-1. A Summary of Test Results is included in Exhibit 5.

8. Clinical Data

Clinical data are not required.

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9. Sterility Information:

The UltrAblator™ Electrode will be supplied sterile, single use, and will be sterilized using Ethylene Oxide as follows:

1. EtO Sterilization Cycle Parameters:

   The UltrAblator™ Electrode is sterilized by using 100% Ethylene Oxide (EtO). Validation of the process will be on file at Linvatec, Largo, Florida.

   NOTE: Sterilization of product will be processed at Cosmed, New Jersey. Other contract sterilization facilities and/or processes may be used in the future.

2. Residual levels for ETO, ECH, & EG will meet the requirements per FDA Proposed Rule, page 27482, dated June 23, 1978, and ISO 10993-7-1995 "Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals".

3. Sterility Assurance Level (SAL): 10^{-6}

4. Sterility Validation Method will be per ANSI/AAMI/ISO 1135-1994 Method C, Half Cycle Method.

10. Packaging

The UltrAblator™ Electrode is placed into protective mounting card fabricated from .010" High Density Polyethylene (HDPE), natural color.

The electrode is then placed into a chevron style peel pouch with one layer consisting of DuPont Tyvek®, 1073B medical grade (uncoated), and the other layer consisting of .002" thick translucent coextruded film consisting of polyethylene/polymar (.0015" polyethylene and .0005" polymer). The pouch is then heat sealed to create a sterile barrier. A label will be applied to the pouch.

Kit components ("pencil" and dispersive pad) are packed along with the pouched electrode into a folding carton, reverse tuck style, consisting of .024" thick Clay-Coated Newsback (CCN) fiberboard. A label will be applied to the Kit box.

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11. Substantial Equivalence Information:

The UltrAblator™ Electrode is substantially equivalent to:

1. Ablator Electrode (Exhibit 6)
   Catalog Number : Various
   Company Name : Linvatec Corporation
   510(k) # : K983652

2. ESA Electrode (Exhibit 7)
   Catalog Number : Various
   Company Name : Linvatec Corporation
   510(k)# : #944992

The similarities/dissimilarities to the predicates are shown in the table on the following page.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 0 2000

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

Re: K993885
Trade Name: UltrAblator™ Electrode
Regulatory Class: II
Product Code: JOS and GEI
Dated: November 15, 1999
Received: November 16, 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,

for Stephen Rhodes

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

Enclosure

510(k) Number (if known): K993885

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. Arthroscopic surgery includes the following:

Knee

1. Meniscectomy
2. Lateral Release
3. Chondroplasty
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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. 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

Intended Use (Continued)

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)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993885

Prescription Use X OR Over-the-Counter Use___

(Per 21 CFR 801.109)

(Optional Format 1-2-96)