

K991830

08 20 1999

August 5, 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 HeatWave™ Electrode, 510(k) Number K991830.

#### **A. Submitter**

Linvatec Corporation  
11311 Concept Boulevard  
Largo, Florida 33773-4908

#### **B. Company Contact**

Laura Seneff  
Manager, Regulatory Affairs

#### **C. Device Name**

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

#### **D. Predicate/Legally Marketed Devices**

TAC™ Probes  
ORATEC Interventions, Inc.

ArthroWand CAPS  
ArthroCare Corporation

#### **E. Device Description**

The HeatWave™ Electrode is a sterile, single-use, monopolar electrode designed to be used in conjunction with an electrosurgical generator via an electrosurgical pencil and a dispersive pad. The HeatWave Electrode will be sold individually and/or in a kit containing an electrode, electrosurgical pencil and an electrosurgical dispersive pad.

#### **F. Intended Use**

The HeatWave Electrode is intended to be used for electro-coagulation of soft tissue in shoulder, ankle, wrist, elbow and knee arthroscopic procedures.

#### **G. Substantial Equivalence**

The HeatWave Electrode is substantially equivalent in design, function and intended use to the TAC™ Probes (ORATEC Interventions, Inc.) and the ArthroWand CAPS (ArthroCare Corporation).

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

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

Summary of Safety and Effectiveness

HeatWave Electrode

510(k) # K991830

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**CHART OF SIMILARITIES AND DISSIMILARITIES**

Company	Device Name	Intended Use	Material	Single-Use Reusable Method of Sterilization	Design/Dimensions
<b>NEW PRODUCT</b> Linvatec	HeatWave™ Electrode	Electro-coagulation of soft tissue in shoulder, ankle, wrist, elbow and knee arthroscopic procedures	Tip/Shaft: 303 Stainless Steel Shrink Tube: Kynar Hub: Polystyrene	Single-Use ETO	Diameter: 2.3mm 3.0mm 4.0mm Working length: 4-8½in. Monopolar
<b>PREDICATE</b> ORATEC Interventions, Inc. 510(k)# K984185	TAC-S™ Monopolar Cautery Probe	Electro-coagulation of soft tissue in shoulder, ankle, wrist, elbow and knee arthroscopic procedures	Tip/Shaft: 303 Stainless Steel Shrink Tube: Teflon Hub/Connector: ABS Plastic	Single Use Sterilization Method Unknown	Diameter: 2.0mm Working Length: 6 in. Monopolar
<b>PREDICATE</b> ArthroCare Corporation 510(K) # Unknown	ARTHROWAND CAPS	Electro-coagulation of soft tissue during arthroscopic procedures	Shaft: 300 Series Stainless Steel Tip: Ceramic Hub/Connector: ABS Plastic	Single-Use Sterilization Method Unknown	Degree/Diameter: 25°/3.0mm 35°/3.0mm Working length: 5.0 in. Bipolar



AUG 20 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K991830  
Trade Name: HeatWave™ Electrode  
Regulatory Class: II  
Product Code: JOS  
Dated: August 5, 1999  
Received: August 10, 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.

Page 2 – Ms. Laura Seneff

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* 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

August 5, 1999

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510(k) Number (if known): K991830

Device Name: HeatWave™ Electrode

Indications for Use:

The HeatWave Electrode is intended to be used for electro-coagulation of soft tissue in shoulder, ankle, wrist, elbow and knee arthroscopic procedures.

(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)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K991830

(Optional Format 1-2-96)