

OCT 25 1999



### 510(k) Summary

ORATEC®

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is:           K991140          

A. **Submitter:**  
ORATEC Interventions, Inc.  
3700 Haven Court  
Menlo Park, CA 94025

Phone: (650) 369-9904  
Fax: (650) 369-9902

Contact: Sheila Ramerman  
Date Prepared: October 7, 1999

B. **Device Names:**  
Proprietary Name: ORATEC Interventions, Inc., VULCAN™ EAST™  
ElectroThermal Arthroscopy System and Accessories  
Common Name: Electrosurgical generator and accessories  
Classification Name: Electrosurgical and Coagulation Unit and Accessories

C. **Legally Marketed Device:**  
  
The ORATEC Vulcan EAS ElectroThermal Arthroscopy System and Accessories are substantially equivalent to the ValleyLab Force FX Electrosurgical Generator (K944602), currently manufactured and distributed by ValleyLab Inc.

D. **Device Description:**  
  
The ORATEC Interventions, Inc., VULCAN EAS ElectroThermal Arthroscopy System generator is a single channel, 200-watt, electrothermal generator that offers finely controlled radiofrequency output for the electrocoagulation, cutting, and ablation of soft tissue during a variety of arthroscopic procedures. The unit is specifically designed to be used with ORATEC electrothermal, electrosurgical, and ablation probes. Temperature and impedance monitoring are provided to assist the surgeon by automatically adjusting energy delivery to maintain effective tissue heating during temperature controlled applications.

Accessories provided with the Vulcan EAS include:

- AC power cord
- Probe extension cable
- Dual-pedal footswitch control

ORATEC  
Interventions,  
Inc.

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Menlo Park, CA  
94025

Phone:  
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Each generator is also accompanied by Instructions for Use and a warranty registration card.

E. Intended Use:

The Vulcan EAS ElectroThermal Arthroscopy System and Accessories are intended to be used for general surgical purposes, including orthopedic and arthroscopic applications, in coagulation, ablation, and hemostasis of soft tissues in combination with ORATEC temperature controlled, cutting, and ablation probes.

The VULCAN EAS ElectroThermal Arthroscopy System and Accessories are intended for use by qualified medical personnel trained in the use of electro-surgical equipment.

Contraindications for Use:

The use of the VULCAN EAS ElectroThermal Arthroscopy System and Accessories are contraindicated, when in the judgment of the physician, an electro-surgical procedure would be contrary to the best interest of the patient.

F. Comparison with the Predicate Device:

The Vulcan EAS and the ValleyLab Force FX are similar in that:

- Both can be used for coagulation (fulguration), cutting, or ablation (desiccation) of tissues
- Both can be used with monopolar and bipolar electro-surgical devices;
- Both measure impedance (resistance) to control power output;
- Both offer preset temperature and power combinations;
- Both offer neutral electrode monitoring circuits;
- Both are software-controlled RF generators.

The Vulcan EAS and the ValleyLab Force FX differ in that:

- The Vulcan offers temperature control, whereas the Force FX does not
- The Vulcan offers auto probe recognition, whereas the Force FX does not;
- The Vulcan offers a remote control of generator settings, whereas the Force FX does not;
- The Vulcan offers a remote display of generator settings, whereas the Force FX does not;
- The Vulcan can accommodate an auxiliary thermocouple, whereas the Force FX cannot;
- The Vulcan is designed for electro-surgery only, whereas the Force FX is also capable of ultrasonic surgery.

Based on the data and information presented here, the ORATEC VULCAN EAS ElectroThermal Arthroscopy System and Accessories are substantially equivalent to the ValleyLab Force FX Electro-surgical Generator manufactured and distributed by Valley Lab Inc.

7



OCT 25 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Sheila Ramerman  
Director, Regulatory and Clinical Affairs  
Oratec Interventions, Inc.  
3700 Haven Court  
Menlo Park, California 94025

Re: K991140  
Trade Name: VULCAN™ EAST™ ElectroThermal Arthroscopy System  
and Accessories  
Regulatory Class: II  
Product Code: GEI  
Dated: July 26, 1999  
Received: July 27, 1999

Dear Ms. Ramerman:

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.

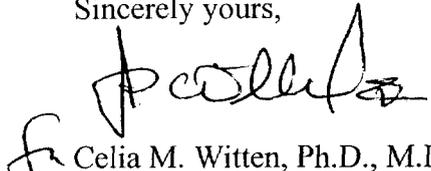
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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. Sheila Ramerman

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

510(k) Number:           K991140          

Device Name:           VULCAN™ EAS™ ElectroThermal Arthroscopy System and Accessories          

**Indications for Use:**

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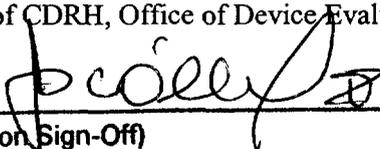
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PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF  
NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number           K991140          

Prescription Use  ~~\_\_\_\_\_~~  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)