JAN 18 2000

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: K994-333

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: December 16, 1999

B. Device Names:

Classification name	Electrosurgical and Coagulation Unit and Accessories
Common/usual name	Electrosurgical generator and accessories
Proprietary name	ORA-50 ElectroThermal System and Accessories

C. Predicate Device: Model ORA-50 ElectroThermal Generator, K964071

D. Device Description:

The ORATEC Interventions ORA-50 ElectroThermal System ("ORA-50") is a single channel, 50-watt, electrothermal generator that offers finely controlled radiofrequency output for use during a variety of arthroscopic procedures. The ORATEC ORA-50 is specifically designed for use with ORATEC cutting and temperature controlled probes.

Temperature and impedance monitoring are provided to assist the physician by automatically adjusting energy delivery to maintain effective tissue heating during temperature-controlled applications. Preset temperature and power settings in the generator software offer the convenience of quickly configuring the generator for use.

ORATEC
Interventions, Inc.
3700 Haven Court
Menlo Park, CA
94025
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(650) 369-9904
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E. Intended Use:

The ORA-50 ElectroThermal System and Accessories are intended to be used for general surgical purposes, including orthopedic and arthroscopic applications, in coagulation of soft tissues. The ORA-50 ElectroThermal System and Accessories are intended for use by qualified medical personnel trained in the use of electrosurgical equipment.

Contraindications for Use: The ORA-50 ElectroThermal System and Accessories are contraindicated, when in the judgement of the physician, an electrosurgical procedure would be contrary to the best interest of the patient.

F. Comparison with the Predicate Device:

The ORA-50 System is a hardware and software modification of the Model ORA-50 Generator (K964071). The ORA-50 System and the Model ORA-50 ElectroThermal Generator have the same intended use and use the same operating principle.

Based on the data and information presented here, the modified ORA-50 System and Accessories are substantially equivalent to the ORA-50 ElectroThermal System and Accessories currently manufactured and distributed by ORATEC Interventions, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 18 2000

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

Re: K994333
Trade Name: ORA-50 ElectroThermal System and Accessories
Regulatory Class: II
Product Code: HRX and GEI
Dated: December 20, 1999
Received: December 23, 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 (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 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): K994333

Device Name: ORATEC Interventions ORA-50 ElectroThermal System and Accessories

Indications for Use:

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PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

Stephen Pluchik

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K994333

Prescription Use ✓ or Over-The-Counter Use _____
(Optional format 1-2-96)