MAY 17 1999

510(k) Summary

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: K990474

A. Submitter:

Oratec Interventions, Inc.
3700 Haven Court
Menlo Park, CA 94025

Phone: (650) 369-9904
Fax: (650) 369-9905

Contact: Sheila Ramerman
Date Prepared:

B. Device Names:

Proprietary Name:	ORATEC® Interventions, Inc., ORA-50 S Programmable ElectroThermal Spine System and Accessories
Common Name:	Electrosurgical generator and accessories
Classification Name:	Electrosurgical and Coagulation Unit and Accessories

C. Legally Marketed Device:

The ORATEC ORA-50 S Programmable ElectroThermal Spine System and Accessories are substantially equivalent to the ORATEC ORA-50 ElectroThermal Generator and Accessories ("ORA-50", K964071), currently manufactured and distributed by ORATEC Interventions, Inc.

D. Device Description:

The ORATEC Interventions, Inc., ORA-50 S Programmable ElectroThermal Spine System generator is a single channel, 50-watt, electrothermal generator that offers finely controlled radiofrequency output for the electrocoagulation, cutting, and ablation of soft tissue during a variety of spine procedures. The unit is specifically designed to be used with ORATEC spine 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. A Programmed Temperature Profile mode specifically designed for use with the ORATEC SpineCATH™ device ("SpineCATH Intradiscal Catheter", K974464) is also included.

Accessories provided with the ORA-50 SP include:

- AC power cord
- Single-pedal foot pedal control

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

E. Intended Use:

The ORA-50 S Programmable ElectroThermal Spine System and Accessories are intended to be used for general surgical purposes in coagulation of soft tissues, in combination with ORATEC thermal/coagulating probes.

The ORA-50 S Programmable ElectroThermal Spine System and Accessories are intended for use by qualified medical personnel trained in the use of electrosurgical equipment.

Contraindications for Use:
The use of the ORA-50 S Programmable Spine System and Accessories are contraindicated, when in the judgment 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 SP and the ORA-50 are similar in that:
- Both deliver 50 or fewer watts of power;
- Both control and monitor temperature;
- Both monitor impedance;
- Both use monopolar delivery of RF energy;
- Both utilize preset settings for power and/or temperature to deliver RF energy;
- Both are software-controlled devices;
- Both have the same intended use.

The ORA-50 SP and the ORA-50 differ in that:
- The ORA-50 SP software was modified to facilitate use with the ORATEC SpineCATH device (K974464) and the ORATEC ORAflex device (K973158);
- The ORA-50 SP has a connection and a display for an Auxiliary Thermocouple, whereas the currently marketed ORA-50 does not;
- The ORA-50 SP probe extension cable contains a fourth active pin for use with the SpineCATH device, whereas the ORA-50 probe extension cable does not;
- The ORA-50 SP probe connector has been modified to accept the modified extension cable.

Based on the data and information presented here, the ORATEC ORA-50 S Programmable ElectroThermal Spine System and Accessories are substantially equivalent to the ORA-50 ElectroThermal Generator and Accessories 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

MAY 17 1999

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

Re: K990474
Trade Name: ORA-50 S Programmable ElectroThermal Spine System and Accessories
Regulatory Class: II
Product Code: GEI and HRX
Dated: February 12, 1999
Received: February 16, 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,

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: K990474

Device Name: ORA-50 S Programmable ElectroThermal Spine System and Accessories

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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 K990474

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)