JUN 2 3 1999

ORATEC™

510(k) Summary

ORATEC Interventions, Inc.
Deflectable Electrosurgical Probes

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: K991190

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: June 18, 1999

B. Device Names:

Proprietary Name:	ORATEC® Interventions, Inc., Deflectable Electrosurgical Probes
Common/usual Name:	Electrosurgical Accessory
Classification Name:	Electrosurgical Device

C. Predicate Device: ORATEC® Interventions, Inc., Electrosurgical Probes, K965007

D. Device Description:
The Deflectable Electrosurgical Probes are disposable, monopolar electrosurgical devices designed to coagulate or to cut tissues. They provide minimally invasive access to the targeted tissues. The Deflectable Electrosurgical Probes are used in conjunction with ORATEC ElectroThermal generators to deliver monopolar radiofrequency (RF) energy for electro-coagulation and cutting of soft tissues.

The Deflectable Electrosurgical Probes incorporate:
- A shaft with an RF energized tip to perform tissue coagulation;
- Optional tip configurations for various general tissue coagulation and cutting uses;

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- A controllable, deflectable tip at the distal end of the probe to allow easier access to all tissue surfaces;
- A handle, with cable connector and deflecting mechanism at the proximal end.

E. Intended Use:

The Deflectable Electrosurgical Probes are disposable electrosurgical devices designed for general surgical use in procedures where electro-coagulation and cutting of soft tissues is desired. They are designed to be used with ORATEC ElectroThermal generators.

F. Comparison with the Predicate Device:

The ORATEC Interventions Deflectable Electrosurgical Probes and the ORATEC Interventions Electrosurgical Probes are the same in that:

- both provide minimally invasive access to targeted tissues;
- both deliver monopolar radiofrequency energy for electro-coagulation and cutting of soft tissues;
- both consist of an insulated shaft with an RF energized tip;
- both are designed to be used with ORATEC radiofrequency generators.

The Deflectable Electrosurgical Probes and the Electrosurgical Probes differ in that:

- the Deflectable Probes may have different physical dimensions than the Electrosurgical Probes;
- the Deflectable Probes may use different tip or insulating materials than the Electrosurgical Probes;
- the Deflectable Probes have a controllable, deflectable distal tip to allow orientation of the tip during use, whereas the Electrosurgical Probes have a malleable distal tip that must be manually bent before use.

Based on the information presented here, the ORATEC Interventions Inc., Deflectable Electrosurgical Probes are substantially equivalent to the Electrosurgical Probes 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

JUN 23 1999

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

Re: K991190
Trade Name: Deflectable Electrosurgical Probes
Regulatory Class: II
Product Code: GEI
Dated: April 7, 1999
Received: April 8, 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.

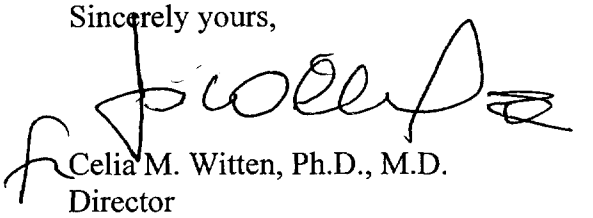
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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

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Date Prepared: June 18, 1999

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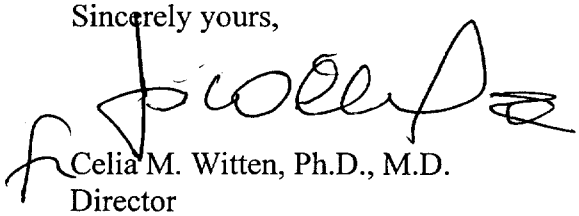

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
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Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Page _____ of _____

510(k) Number (if known): K991190

Device Name: Oratec™ Interventions Deflectable Electrosurgical Probes

Indications for Use:

The Deflectable Electrosurgical Probes are disposable, monopolar electrosurgical devices intended for general surgical use in procedures where electro-coagulation and cutting of soft tissues is desired. They are designed to be used with ORATEC ElectroThermal generators.

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)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991190