SEP 13 1999

510(k) Summary

ORATEC Interventions, Inc.
Bipolar Ablation Probes

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: K991218

A. Submitter:

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

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fax: (650) 369-9902

Contact: Sheila Ramerman
Date Prepared: June 25, 1999

B. Device Names:

Proprietary Name:	Bipolar Ablation Probes
Common/usual Name:	Electrosurgical Accessory
Classification Name:	Electrosurgical Device

C. Predicate Device: ArthroCare Ablation Probes, ArthroCare Corporation

D. Device Description:
The ORATEC Bipolar Ablation Probes are disposable, bipolar electrosurgical devices designed to cut or ablate soft tissues. They provide minimally invasive access to the targeted tissues. The Bipolar Ablation Probes are used in conjunction with the ORATEC Vulcan™ EAS™ RF generator to deliver bipolar radiofrequency (RF) energy for ablation of soft tissues.

The probes consist of an insulated shaft, an insulated power electrode, a return electrode, and a handle. Probes may incorporate suction capability for the removal of ablated tissue from the surgical site.

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E. Intended Use:

The Bipolar Ablation Probes are disposable, bipolar electrosurgical devices intended to be used for ablation and hemostasis of soft tissues in arthroscopic procedures. They are designed to be used with the ORATEC Vulcan EAS generator.

F. Comparison with the Predicate Device:

The ORATEC Interventions Bipolar Ablation Probes and the ArthroCare Ablation Probes are the same in that:

- both provide minimally invasive access to targeted tissues;
- both deliver bipolar radiofrequency energy for ablation of soft tissues;
- both are capable of suction;
- both are provided sterile and are designed for single-use only.

The ORATEC Bipolar Ablation Probes and the ArthroCare Ablation Probes differ in that:

- The ORATEC probes may be of different physical dimensions than the ArthroCare probes;
- the ORATEC probes may use different electrode, shaft, or insulating materials than the ArthroCare probe;
- the ORATEC probe shafts may have a malleable distal end to allow orientation of the tip during use, whereas the ArthroCare probe does not;
- the ORATEC probes typically consist of one electrode to deliver RF energy whereas the ArthroCare probes typically consist of multiple electrodes.

These design differences do not raise any new questions of safety or effectiveness. The ORATEC Bipolar Ablation Probes performed equivalently to the predicate devices in bench and in clinical testing.

Based on the information presented here, the ORATEC Bipolar Ablation Probes are substantially equivalent to the ArthroCare Ablation Probes manufactured and distributed by ArthroCare Corporation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 3 1999

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

Re: K991218
Trade Name: ORATEC® Bipolar Ablation Probes
Regulatory Class: II
Product Code: GEI
Dated: July 28, 1999
Received: July 29, 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 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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510(k) Number (if known): K991218

Device Name: ORATEC Interventions Bipolar Ablation Probes

Indications for Use:

The Bipolar Ablation Probes are disposable, bipolar electrosurgical devices intended to be used for ablation and hemostasis of soft tissues in arthroscopic procedures. They are designed to be used with the ORATEC® Vulcan™ EAS™ generator.

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 K991218

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)