

JUN 14 1999

510(k) Summary

ORATEC Interventions, Inc.
Deflectable TAC ElectroThermal™ Probe

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: K990859

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 11, 1999

B. Device Names:

Proprietary Name: Deflectable TAC™ ElectroThermal Probe
Common/usual Name: Electrosurgical Accessory
Classification Name: Electrosurgical Device

C. Predicate Device: TAC-S™ Monopolar Cautery Probe, K963157, K984185

D. Device Description:

The Deflectable TAC ElectroThermal Probe is a disposable, monopolar electrosurgical device designed to create controlled coagulative lesions in tissues. It provides minimally invasive access to the targeted tissues. The Deflectable TAC probe is used in conjunction with ORATEC ElectroThermal RF generators to deliver monopolar radiofrequency (RF) energy for electro-coagulation of soft tissues.

The Deflectable TAC probe incorporates:

- A shaft with an RF energized tip for percutaneous or arthroscopic access to perform tissue coagulation;

510(k) Premarket Notification

ORATEC Deflectable TAC ElectroThermal Probe – Summary of Safety and Effectiveness

- A thermocouple at the distal end of the shaft for measuring tip temperature during RF energy delivery;
- 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 TAC ElectroThermal probe is a disposable electrosurgical device intended to be used for electro-coagulation of soft tissues in arthroscopic procedures. It is designed to be used with ORATEC ElectroThermal generators.

F. Comparison with the Predicate Device:

The ORATEC Interventions Deflectable TAC probe and the ORATEC Interventions TAC-S probe are the same in that:

- both provide minimally invasive access to targeted tissues;
- both deliver monopolar radiofrequency energy for electro-coagulation of soft tissues;
- both consist of an insulated shaft with an RF energized tip;
- both contain a thermocouple in the distal end for measuring tip temperature during RF delivery;
- both are designed to be used with ORATEC radiofrequency generators.

The Deflectable TAC and the TAC-S differ in that:

- the Deflectable TAC probe has different physical dimensions than the TAC-S probe;
- the Deflectable TAC may use different tip or insulating materials than the TAC-S probe;
- the Deflectable TAC has a controllable, deflectable distal tip to allow orientation of the tip during use, whereas the TAC-S has a malleable distal tip that must be manually bent before use;
- the Deflectable TAC can be used in endoscopic and arthroscopic surgical settings, whereas the TAC-S is designed for arthroscopic surgical settings.

Based on the information presented here, the Deflectable TAC ElectroThermal Probe is substantially equivalent to the TAC-S Monopolar Cautery Probe manufactured and distributed by Oratec Interventions, Inc.



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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: K990859
Trade Name: Deflectable TAC Electro Thermal Probe
Regulatory Class: II
Product Code: HRX and GEI
Dated: March 15, 1999
Received: March 16, 1999

Dear Ms. Ramerman:

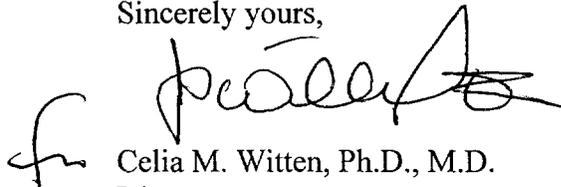
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". To the left of the signature is a small, stylized handwritten mark that looks like the letter "f".

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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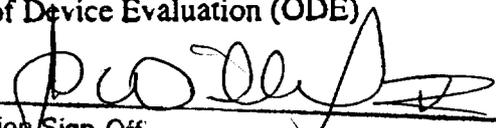
Device Name: Oratec Interventions Deflectable TAC™ ElectroThermal™ Probe

Indications for Use:

The Deflectable TAC ElectroThermal probe is a disposable, monopolar electrosurgical device intended to be used for electro-coagulation of soft tissues in arthroscopic procedures. It is 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)


(Division Sign-Off)
Division of **General Restorative Devices**
510(k) Number K990859

Prescription Use f
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)