

DEC 16 1998

Special 510(k): Device Modification
ORATEC TAC-S Monopolar Cautery Probe

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: K984185

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: November 18, 1998

B. Device Names:

Classification Name: Electrosurgical Device
Common/usual Name: Electrosurgical Accessory
Proprietary Name: TAC-S™ Monopolar Cautery Probe Family:
TAC-S Monopolar Cautery Probe
MiniTAC™-S Monopolar Cautery Probe ✓
MicroTAC-S™ Monopolar Cautery Probe ✓

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

D. Device Description:

The ORATEC Interventions TAC-S, MiniTAC-S, and MicroTAC-S Monopolar Cautery Probes are single-use electrosurgical devices designed for use in arthroscopic procedures where electro-coagulation of soft tissues is desired. They are designed to provide minimally invasive access to the targeted tissue, and to deliver radio-frequency energy in a controlled fashion. The modified probes consist of the following features:

- a shaft with a radiofrequency-energized tip for percutaneous or intraoperative access to perform tissue coagulation;
- a thermocouple at the distal end of the shaft for measuring tip temperature during RF energy delivery;
- handle and cable connection receptacle at the proximal end;
- accessory connector cables which are designed to fit standard RF control units with temperature and impedance feedback.

The only modifications made from the predicate device are:

- Using teflon as an insulating material on the probe shaft.
- Decreasing handle, probe shaft, and electrode dimensions for the smaller versions.

E. Intended Use:

The TAC-S™ Monopolar Cautery Probe is a disposable electrosurgical device intended to be used in arthroscopic procedures where electro-coagulation of soft tissues is desired. It is intended to be used with Oratec™ Interventions ElectroThermal™ Generators.

F. Comparison with the Predicate Device:

The TAC-S Monopolar Cautery Probe and the modified TAC-S probes are similar in that they:

- have the same indicated use;
- use the same operating principle;
- use the same basic probe design;
- use the same shaft material;
- are packaged and sterilized in the same manner.

The TAC-S Monopolar Cautery Probe and the modified TAC-S probes differ in that the modified TAC-S probes:

- use teflon as an insulating material on the probe shaft.
- have smaller probe shaft dimensions and electrode surface areas.

Based on the data and information presented here, the modified TAC-S probes are substantially equivalent to the existing TAC-S probes 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, Incorporated
3700 Haven Court
Menlo Park, California 94025

Re: K984185
Trade Name: Mini TAC-S™ Monopolar Cautery Probe and
Micro TAC-S™ Monopolar Cautery Probe
Regulatory Class: II
Product Code: GEI
Dated: November 20, 1998
Received: November 23, 1998

Dear Ms. Ramerman:

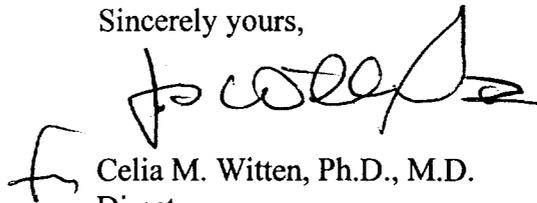
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

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". The signature is stylized and written over a faint, larger version of the same signature.

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 (if known): K984185

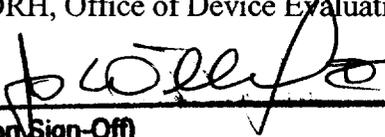
Device Name: Oratec™ Interventions TAC-S™ Monopolar Cautery Probes

Indications for Use:

The TAC-S™ Monopolar Cautery Probes are disposable electrosurgical devices intended to be used in arthroscopic procedures where electro-coagulation of soft tissues is desired. They are intended to be used with Oratec™ Interventions 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 K984185

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)