

JUL 30 1999

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



510(k) Summary

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: K 99 2408

A. Submitter:

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

Telephone: (650) 369-9904
Fax: (650) 369-9902

Contact: Sheila Ramerman
Date Prepared: July 19, 1999

B. Device Names:

Classification Name: Electrosurgical Device
Common/usual Name: Electrosurgical Probes
Proprietary Name: Electrosurgical Probes Family:
Ligament Chisels™
MicroLigament Chisels™
Ablator™ Probes

C. Predicate Device: Electrosurgical Probes, K965007

D. Device Description:

The ORATEC Interventions Electrosurgical Probes are single-use electrosurgical devices designed for use in minimally invasive procedures where electro-coagulation and cutting 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 minimally invasive access to perform tissue coagulation and/or cutting;
- different electrode tip configurations to provide optimal access to tissue;
- handle and cable connection receptacle at the proximal end.

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The modifications made from the predicate device are:

- Adding alternate electrode tip materials;
- Adding alternate insulating materials on the probe shaft;
- Adding different tip configurations;
- Decreasing handle, probe shaft, and electrode dimensions for the smaller versions.

E. Intended Use:

The Electrosurgical Probes are disposable electrosurgical devices intended to be used in general surgical procedures where electro-coagulation and cutting of soft tissues is desired. They are intended to be used with ORATEC Interventions ElectroThermal™ Generators.

F. Comparison with the Predicate Device:

The Electrosurgical Probes and the modified Electrosurgical 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 Electrosurgical Probes and the modified Electrosurgical Probes differ in that the modified probes:

- use alternate electrode tip materials;
- use alternate insulating materials on the probe shaft;
- use different tip configurations;
- have smaller probe shaft dimensions and electrode surface areas.

Based on the data and information presented here, the modified Electrosurgical Probes are substantially equivalent to the existing Electrosurgical Probes manufactured and distributed by ORATEC Interventions, Inc.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 30 1999

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

Re: K992408
Trade Name: ORATEC Interventions Electrosurgical Probes
Regulatory Class: II
Product Code: GEI
Dated: July 19, 1999
Received: July 20, 1999

Dear Ms. Ramerman:

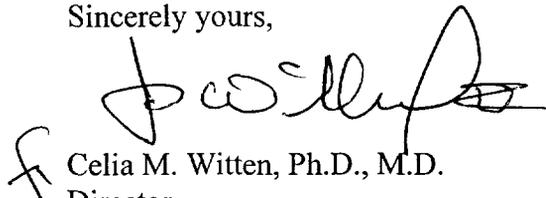
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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". The signature is written in a cursive style with a large initial "C" and "W".

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

510(k) Number (if known): K 992408

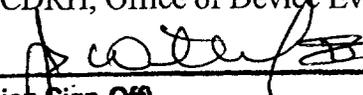
Device Name: ORATEC Interventions Electrosurgical Probes

Indications for Use:

The Electrosurgical Probes are disposable electrosurgical devices intended to be used in general surgical procedures where electro-coagulation and cutting 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 K992408

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

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