NOV 23 1998

K982971

SUMMARY OF SAFETY AND EFFECTIVENESS

ORATEC™

This 510(k) safety and effectiveness summary is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR §807.92.

General Information

Manufacturer:	Oratec Interventions, Inc. 3700 Haven Court Menlo Park, CA 94025 Phone: (650) 369-9904
Contact Person:	Sheila Ramerman Oratec Interventions, Inc.
Date Prepared:	August 24, 1998

Device Information

Classification Name:	Electrosurgical cutting and coagulation device and accessories
Common/Usual Name:	Electrosurgical accessory
Proprietary Name:	Oratec Interventions, Inc., TAC-C™ Monopolar Cautery Probe
Device Class:	II, at 21 CFR 878.4400
Product Code:	79GEI

Intended Use

The Oratec TAC-C™ Monopolar Cautery Probe is a single-use electrosurgical device intended to be used to create controlled coagulative lesions in tissues. It is intended to be used only in conjunction with the Oratec Electrothermal Generator.

Product Description

The Oratec TAC-C™ Monopolar Cautery Probe has a tip electrode oriented at a right angle from the axis of the shaft in the shape of a half dome. This tip configuration provides the ability to coagulate tissues that lie in the same plane as the angle of the shaft. The probe shaft is made of stainless steel which is malleable and may be bent to any shape that is necessary. Only the tip is heated; the adjacent/rest of the tube is insulated with a protective insulative coating. The proximal end of the shaft is attached to a plastic handle.

ORATEC
Interventions, Inc.
3700 Haven Court
Menlo Park, CA 94025
Phone:
(650) 369-9904
Fax:
(650) 369-9905

Substantial Equivalence

The TAC-C™ and TAC-S™ probes are similar in that:

- Both probes are designed for general surgical use;
- Both probes are designed to create controlled coagulative lesions in tissues;
- Both probes use the T-type (combination of copper and constantan) thermocouple that terminates with the probe tip; and,
- Both probes are the same size, with the same shaft length, diameter, and handle.

The TAC-C™ and TAC-S™ probes differ in that:

- The TAC-C™ tip is oriented at a right angle to the axis of the shaft, whereas the TAC-S™ is oriented in the same plane as the shaft;
- The TAC-C™ tip is formed in the shape of a half-dome, whereas the TAC-S™ tip is formed in the shape of a bullet;
- The TAC-C™ tip is made of silver solder, whereas the TAC-S™ tip is made of stainless steel; and,
- The TAC-C™ tip's surface area is smaller than the surface area of the TAC-S™ tip.

Table III-C, in Section III, lists the similarities and differences between the two devices.

Biocompatibility

The Oratec TAC -C™ Monopolar Cautery Probe meets the requirements of ISO 10993 for Limited Contact, External Communicating Devices, Tissue/Bone/Dentin Communicating.

Summary

Based upon the information described in this submission, the Oratec TAC-C™ Monopolar Cautery Probe is substantially equivalent to the Oratec TAC-S™ Monopolar Cautery Probe.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 23 1998

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

Re: K982971
Trade Name: TAC-C™ Monopolar Cautery Probe
Regulatory Class: II
Product Code: GEI
Dated: August 24, 1998
Received: August 25, 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 legally marketed predicate 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 requirements, 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/dsma/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

INDICATIONS FOR USE

510(k) Number (if known): K982971

Device Name: TAC-C™ Monopolar Cautery Probe

Indications for Use:

The Oratec TAC-C™ Monopolar Cautery Probe is a disposable electrosurgical device designed to create controlled coagulative lesions in tissues.

Contraindications for Use:

None known.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X 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 K982971