

K974464

MAR 19 1998 **510(k) Summary of Safety and Effectiveness
SpineCATH Intradiscal Catheter**

This 510(k) safety and effectiveness summary is being submitted in accordance with the requirements of Safe Medical Devices Act 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: Michael Kwan, Ph.D.
Oratec Interventions, Inc.

Date Prepared: December 1, 1997

Device Information

Classification: Class II

Trade Name: SpineCATH Intradiscal Catheter

Classification Name: Electrosurgical Device and Accessories
(878.4400)

Intended Use

The SpineCATH Intradiscal Catheter is intended for use for the coagulation and decompression of disc material to treat symptomatic patients with annular disruption of contained herniated discs.

Product Description

The SpineCATH Intradiscal Catheter is a single use electrothermal device utilizing a flexible shaft design and thermally activated tip. The entire length of the shaft is fully insulated and when activated, only the tip delivers thermal energy. In addition, a thermocouple is located at the tip of the catheter to monitor temperature. The SpineCATH Intradiscal Catheter is for use only with the Oratec generator.

Substantial Equivalence

The SpineCATH Intradiscal Catheter is substantially equivalent in design to the Oratec EndoTAC Monopolar Cautery Probe (K972358). The intended use of the SpineCATH Intradiscal Catheter, decompression of intervertebral discs, is substantially equivalent to currently available mechanical and laser devices,

including Surgical Dynamics' Nucleotomes (K931109, K942987) and Laserscope's KTP/532 and KTP/YAG Laser Systems (K896183, K913758).

Biocompatibility

The SpineCATH Intradiscal Catheter 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 SpineCATH Intradiscal Catheter has been shown to be substantially equivalent to the Oratec EndoTAC Monopolar Cautery Probe, Surgical Dynamics' Nucleotomes and Laserscope's KTP/532 and KTP/YAG Laser Systems.



Michael Kwan

Oratec Interventions, Inc.
November 26, 1997



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 19 1998

Dr. Michael Kwan
Oratec Interventions, Incorporated
3700 Haven Court
Menlo Park, California 94025

Re: K974464
Trade Name: Oratec SpineCATH Intradiscal Catheter
Regulatory Class: II
Product Code: GEI
Dated: February 4, 1998
Received: February 5, 1998

Dear Dr. Kwan:

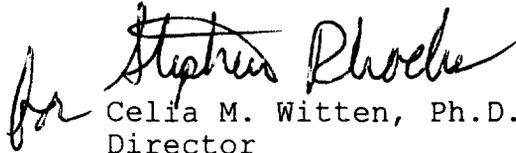
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

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): 974464

Device Name: Oratec SpineCATH Intradiscal Catheter

Indications For Use:

The Oratec SpineCATH Intradiscal Catheter is intended for use for the coagulation and decompression of disc material to treat symptomatic patients with annular disruption of contained herniated discs.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Stephen Rhode

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K974464

Prescription Use X
(Per 21 CFR 801.109)

OR Over-The-Counter Use _____

(Optional Format 1-2-96)