DEC 17 1999

510(k) Summary
ORATEC® SpineCATH™ Intradiscal Catheters

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: K993967

Submitter:

ORATEC® Interventions, Inc.
3700 Haven Court
Menlo Park, CA 94025
Establishment Registration # 2953127

Contact:

Jennifer Brennan
Regulatory Affairs Associate
Telephone: (650) 369-9904
Fax: (650) 369-9902

Date Prepared: November 22, 1999

Device Names:

Classification Name: Electrosurgical device
Common/usual Name: Electrosurgical accessory
Proprietary Name: ORATEC® SpineCATH™ Intradiscal Catheter

Predicate Device: SpineCATH™ Intradiscal Catheter, K974664

Device Description:
The devices described in this 510(k) are sterile, disposable devices intended for use with the ORATEC ElectroThermal Spine System Generator.

Intended 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. The ORATEC SpineCATH™ Intradiscal Catheter is intended for use with ORATEC ElectroThermal™ Spine System Generator.

Safety and Performance:
This submission is a Special 510(k): Device Modification as described in FDA's Guidance document *"The New 510(k) Paradigm- Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications."* In support of this 510(k), ORATEC has provided certification of compliance to 21 CFR 820.30 Design Control requirements, and the results of validation testing (performance testing) for the device modification.

Conclusion:
Based on the indications for use, fundamental scientific technology characteristics, performance, and comparison to the predicate device, the modified SpineCATH Intradiscal Catheter is substantially equivalent to the predicate SpineCATH Intradiscal Catheter under the Federal, Food, Drug and Cosmetic Act. The SpineCATH Intradiscal Catheter is manufactured and distributed by ORATEC Interventions, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 1999

Ms. Jennifer Brennan
Regulatory Affairs Associate
ORATEC Interventions, Inc.
3700 Haven Court
Menlo Park, California 94025

Re: K993967
Trade Name: ORATEC® Spine CATH™ Intradiscal Catheter
Regulatory Class: II
Product Code: GEI
Dated: November 22, 1999
Received: November 23, 1999

Dear Ms. Brennan:

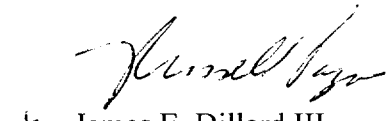
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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



for James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Page _____ of _____ 510(k) Number (if known): K993967

Device Name: ORATEC® SpineCATH™ Intradiscal Catheters

Indications for Use:

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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 K993967

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)