Section 2 - 510(K) Summary of Safety and Effectiveness **JAN 31 2002**

K013622

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.

Contact Person:
Linda Guthrie
Manager, Regulatory Affairs and Compliance
Oratec Interventions, Inc.
3700 Haven Court
Menlo Park, CA 94025

Device Name:
Nucleotomy Catheter

Device Description:
The *Nucleotomy Catheter* is a minimally invasive thermoelectric device. When used in conjunction with the ORA-50 S Generator the *Nucleotomy Catheter* delivers thermal energy to targeted locations inside the disc. The distal portion of the tip is flexible such that the device can maneuver through disc anatomy. The flexible tip contains a resistive metal coil, which produces heat when current flows through it. The device contains a thermocouple for monitoring and controlling the temperature of the treated tissue.

Indications for Use:
The *Nucleotomy Catheter* is intended to be used for the coagulation and decompression of disc material to treat symptomatic patients with contained herniated discs.

Predicate Device:
SpineCATH Intradiscal Catheter K993967, cleared December 28, 1999

Safety and Performance
Performance and biocompatibility testing were conducted to support this claim of substantial equivalence.

Conclusion
The *Nucleotomy Catheter* has the same technological characteristics and similar intended use as the predicate device. Results of the performance and biocompatibility testing, as presented in this pre-market notification, demonstrate that the *Nucleotomy Catheter* is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 31 2002

Ms. Linda Guthrie
Manager, Regulatory Affairs and Compliance
ORATEC Interventions, Inc.
3700 Haven Court
Menlo Park, California 94025

Re: K013622
Trade Name: Nucleotomy Catheter
Regulation Number: 888.1100; 878.4400
Regulation Name: Arthroscope; Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: HRX; GEI
Dated: October 31, 2001
Received: November 5, 2001

Dear Ms. Guthrie:

We have reviewed your Section 510(k) premarket 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K013622

Device Name: Nucleotomy Catheter

Indications for Use: The Nucleotomy Catheter is intended to be used for the coagulation and decompression of disc material to treat symptomatic patients with contained herniated discs.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013622