



9/16/01

AUG 17 2001

Food and Drug Administration  
Center for Devices and  
Radiological Health  
2098 Gaither Road  
Rockville, MD 20850

**WARNING LETTER**

**VIA FEDERAL EXPRESS**

**VIA FACSIMILE**

Mr. Kenneth Anstey  
President & CEO  
Oratec Interventions, Incorporated  
3700 Haven Court  
Menlo Park, California 94025

Re: SpineCATH™ Intradiscal Catheter,  
Electrothermal Arthroscopy System

Dear Mr. Anstey:

On April 26, 1999 this office issued a Warning Letter to Oratec Interventions, Incorporated (Oratec) for certain off-label claims related to the use of the SpineCATH Intradiscal Catheter (SpineCATH) and the Electrothermal Arthroscopy System (Electrotheramal System). These claims included, but were not limited to the following: low back pain, chronic discogenic lumbar syndrome, degenerative disc disease, treatment of disc-related spinal pathology, and/or claims that treatment with the SpineCATH is equivalent to spinal fusion. From your current web site and from additional promotional materials that have come into our possession, i.e., an Oratec marketing brochure and a journal advertisement, it appears that Oratec is perpetuating some of the same claims that you were previously advised would require a new 510(k) because they significantly change the intended use of the device(s). Examples will be provided below.

The SpineCATH and the Electrothermal System are manufactured by Oratec and are devices as defined within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). The Electrothermal System consists of the following devices: ORA-50 RF (Radiofrequency) Generator and the TAC-S Probe, TAC-C Probe, Mini-TAC Probe, Micro-TAC-S Probe, and Micro-TAC-C Probe.

As previously noted in our letter of April 26, 1999, these devices were cleared under section 510(k) of the Act for the following intended uses:

-The Electrothermal Generator and Accessories – intended to be used in combination with Oratec thermal/coagulation probes for general surgical use, including orthopedic and arthroscopic applications, in coagulating soft tissues.

-TAC-S™ Family (includes: TAC-S, Mini-TAC-S, Micro-TAC-S) - intended for use in arthroscopic procedures where electro-coagulation of soft tissues is desired.

-TAC-C™ - intended to be used as a single-use electrosurgical device to create controlled coagulative lesions in tissues.

-SpineCATH™ - intended for the coagulation and decompression of disc material to treat symptomatic patients with annular disruption of contained herniated discs.

The materials currently reviewed by our office include: (1) the Oratec web site (as of August 16, 2001) at the Internet address <http://www.oratec.com>; (2) a SpineCATH marketing brochure #770004, Rev. 03, 12/00 titled, Oratec. This is the Company that Developed the Technology that Revolutionized the Treatment for those with Low Back Pain that Gets the Patient Up and Running that Much Faster; and, (3) an Oratec advertisement titled, IDET (Intradiscal Electrothermal Therapy) which allegedly appeared in the June 2000 issue of Seminars in Spine Surgery Vol. 12, No. 2.

The following claims or representations for SpineCATH and the Electrothermal System continue to appear on your web site; these claims still have not been cleared by the agency:

*-“Introducing IDET Intradiscal ElectroThermal Therapy, a new option in the treatment of degenerative disc disease. SpineCATH is a navigable, intradiscal electrothermal catheter that is placed within a symptomatic disc under fluoroscopic guidance and local anesthesia.” (From the products section of the web site)*

*-“Lower back pain is one of the most common ailments affecting people at some point in their lives. For most people, the pain resolves quickly.... But for many, the pain is a result of a disc degeneration process that is prolonged, severe and for which conventional treatment does not provide the needed relief. It is for these chronic lower back pain sufferers that the SpineCATH Intradiscal Electrothermal (IDET) therapy was developed.” (From the Patients section of the web site)*

In Oratec’s May 7, 1999 response to our previous Warning Letter, you indicated that some of the terms used by medical professionals to describe the presence of contained herniations and annular disruptions include phrases such as degenerative disc disease, chronic discogenic syndrome, internal disc disruption, discogenic pain, and discopathic syndrome. We disagree with that assessment. In addition to annular disruption of contained herniated discs (the cleared intended use), the Office of Device Evaluation has concluded that the claim of degenerative disc disease may also encompass: degenerative arthritis of the facet joints, instability of the motion segment, pain syndromes, and spinal stenosis. The agency considers the claim of degenerative disc disease to be an expansion and broadening of the intended use requiring the submission of a new 510(k).

Additionally, in our follow up letter to Oratec dated October 4, 1999, we advised that whenever Oratec uses the term “lower back pain” it should be qualified with the modifier “lower back pain associated with herniated discs.”

Manufacturers who receive a general clearance for a specific device may not expand that clearance to a more general or broader intended use without first obtaining prior clearance from FDA under the premarket notification process to do so.

We remind you again of the regulations at Title 21, Code of Federal Regulations, Part 801.4 [21 CFR 801.4] which describe the definition of intended use of a device. The intended use is the objective intent of the persons responsible for the labeling of the device. Such objective intent may be shown by the circumstances surrounding the distribution of the product and may be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by labeling claims that the article is, with the knowledge of such persons or their representatives, offered and used for purposes for which it is neither labeled nor advertised.

Marketing the SpineCATH™ and/or the Electrothermal Arthroscopy System for claims of degenerative disc disease or for claims of low back pain without the modifier “associated with herniated discs,” or any other claims for uses which have not been cleared by FDA causes the SpineCATH and Electrothermal Arthroscopy System to be misbranded within the meaning of section 502(o) of the Act, in that a notice or other information respecting the modifications in the intended use of the devices was not provided to FDA as required by section 510(k) of the Act and 21 CFR 807.81(a)(3)(ii), and the devices were not found to be substantially equivalent to a predicate device.

The SpineCATH and Electrothermal Arthroscopy System are also adulterated within the meaning of section 501(f)(1)(B) of the Act in that they are Class III devices under section 513(f), and do not have in effect either approved applications for premarket approval (PMA) pursuant to section 515(a), or approved applications for investigational device exemption (IDE) under section 520(g).

We also note that the Oratec marketing brochure, advertisement, and web site contain additional claims for which we would like to see supporting data. These claims include younger patients who have exhausted their options and require IDET therapy, Oratec’s technology “gets the patient up and running (that) much faster,” thermal energy initiates profound changes in the collagenous and neurovascular annular structures of degenerative discs, precise levels of thermal energy break bonds, contracting and thickening the molecules...and fibers, and, the IDET procedure is a therapeutic option designed for patients with chronic discogenic back pain, who have failed a program of aggressive, non-operative therapy.

Finally, we note that your web site contains a list of upcoming physician training courses scheduled for August 25<sup>th</sup>, October 14<sup>th</sup>, and December 1<sup>st</sup> which purport to provide comprehensive instruction on IDET with the SpineCATH and includes hands-on laboratory training using cadavers and anatomical models. We also note Oratec’s presence at two upcoming trade shows to take place on September 29<sup>th</sup> – October 4<sup>th</sup> in San Diego, CA and October 4<sup>th</sup> – October 6<sup>th</sup> in Palm Desert, CA. Oratec should ensure that your presentations, demonstrations, and lectures at these conferences are strictly limited to the cleared intended uses of your devices.

This letter is not intended to be an all-inclusive list of deficiencies associated with your SpineCath Intradiscal Catheter and/or Electrothermal Arthroscopy System. It is your responsibility to ensure adherence to each requirement of the Act and Federal regulations. The specific violations noted in this letter may represent practices used in other promotion or advertising materials used by your firm. You are responsible for investigating and reviewing these materials to assure compliance with

applicable regulations.

You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office, in writing, within 15 working days of receipt of this letter, outlining the specific steps you have taken to correct the cited violations. Your response should also include all steps being taken to address misleading information currently in the market place and actions to prevent similar violations in the future. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Mr. Steven E. Budabin, Consumer Safety Officer, Promotion and Advertising Policy Staff (HFZ-302), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's San Francisco District Office. Please send a copy of your response to the District Director, Food and Drug Administration, San Francisco District Office (HFR-PA100), 1431 Harbor Bay Parkway, Alameda, California 94502-7070.

Sincerely yours,



Larry D. Spears  
Acting Director  
Office of Compliance  
Center for Devices and  
Radiological Health

cc:  
Sheila Ramerman  
Oratec Regulatory Affairs

bcc:

Drafted: SBudabin: 8/2/01  
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HFA-224	(Records)
HFC-130	
HFC-210	(DCarroll)
HFC-230	
HFC-240	(COMSTAT)
HFI-20	(Press Office)
HFI-35	(with purged cc orig. ltr)
HFR-PA1	(Brenda Holman)
HFR-PA100	(Dennis Linsley)
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HFZ-302	(c/f, s/f, SBudabin FBP (2) #78635)
HFZ-305	(Precedent File)
HFZ-306	(Cathy Condon)
HFZ-343	(Carol Fedorchak)
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HFZ-410	(Martin Yahiro)
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