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APR 26 1999

Food and Drug Administration  
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:

The Food and Drug Administration (FDA) has reviewed your web site and promotional materials for the SpineCATH™ Intradiscal Catheter (SpineCATH™), and the Electrothermal Arthroscopy System. These products are manufactured by Oratec Interventions, Incorporated (Oratec) and are devices as defined within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

According to your web site at the internet address: <http://www.oratec.com>, the Electrothermal Arthroscopic System consists of the following devices: ORA-50 RF Generator and the TAC-S Probe, TAC-C Probe, Mini-TAC Probe, Micro-TAC-S Probe, and Micro-TAC-C Probe.

These devices have been 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.

Your web site makes the following claims or representations for these devices which have not been cleared by the agency:

SpineCATH™

Claims are represented for the off-label treatment of chronic discogenic lumbar pain, degenerative disc disease, disc-related spinal pathology, and low back pain. The Intradiscal Electrothermal Therapy (IDET) identified below results from the use of the SpineCATH™. Specific statements include:

-“Representing innovative thermal technology, Oratec spinal products offer minimally invasive therapies for treatment of disc-related spinal pathology;”

-“The spineCATH IDET therapy: a fluoroscopically guided outpatient thermal procedure for treatment of chronic discogenic lumbar pain syndromes;”

-“Introducing IDET - Intradiscal Electrothermal therapy, a new option in the treatment of degenerative disc disease.”

-“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.”

Additionally, your web page titled, Press also contains references to numerous articles and television programs discussing the SpineCATH™ for uses that have not been cleared. Specifically, we have reviewed a March 15, 1999, Newsweek article titled “Beating the Backache. A New Procedure Could Revolutionize Disc Surgery,” and a video copy of a March 15, 1999, NBC Nightly News piece titled “A New Treatment for Back Pain.” Although the agency does not regulate news-related information, your reference to these materials on your web site results in promotion of the SpineCATH™ for those uses discussed in the news piece.

The Newsweek article discusses the use of IDET™ for the treatment of back pain and states that IDET works at least as well as spinal fusion. The article further states that 80 per cent of recipients of the procedure enjoy greater mobility, enjoy reduced pain, and that half of those taking painkillers became drug free. These claims cannot be used by Oratec until data are presented to, and accepted by, the agency. The NBC NEWS piece also mentions the use of the device for the treatment of chronic back pain. Several other articles on Oratec’s web site also include the word “pain” in their titles, and may not be used because Oratec has not received clearance for the claim of “pain.”

TAC-S™ Family

Oratec's web page titled, Arthroscopy includes the following claims for the use of your electro-surgical probes in the treatment of specific conditions which have not received agency clearance:

- Shoulder and other peripheral joint instability procedures;
- Chondroplasty;
- Synovectomy;
- Subacromial decompression;
- Lateral Retinacular Release.

Manufacturers who receive a general clearance for a specific device may not narrow that clearance to a more specific intended use without first obtaining prior clearance from FDA under the premarket notification process to do so. On November 4, 1998, FDA issued a guidance document for industry titled, General/Specific Intended Use (copy enclosed). The document defines a change from a general to a specific indication for use as follows:

"Any proposed increase in the level of specificity of the indication for use of a medical device. A change in the device's indication for use from general to specific usually results in an indication for use that is narrower than the approved or cleared general use. Such a change or additional indication generally will narrow the indication for use with respect to function, target population, organ or organ tissue system, tissue type, disease entity, or analyte."

Additionally, the regulations at Title 21, Code of Federal Regulations, Part 801.4 [21 CFR 801.4] describe the definition of intended use [objective intent] of a 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™ for claims of low back pain, chronic discogenic lumbar syndrome, degenerative disc disease, treatment of disc-related spinal pathology, or any other claims for uses which have not been cleared by FDA including representations that results from using SpineCATH™ are equivalent to spinal fusion causes the SpineCATH™ to be adulterated within the meaning of section 501(f)(1)(B) of the Act in that it is a Class III

device under section 513(f), and does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a), or an approved application for investigational device exemption (IDE) under section 520(g).

The SpineCATH™ is also 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 device was not provided to FDA as required by 21 CFR 807.81(a)(3)(ii), and the device was not found to be substantially equivalent to a predicate device.

Marketing the Electrothermal Arthroscopy System™ i.e., ORA-50 RF Generator, TAC-S Family, TAC-C, or any other devices that make up the Electrothermal Arthroscopy System, for claims of shoulder and other peripheral joint instability procedures, chondroplasty, synovectomy, subacromial decompression, lateral retinacular release, or for any other off-label claims, causes the devices that make up the system to be adulterated within the meaning of section 501(f)(1)(B) of the Act in that it is a Class III device under section 513(f), and does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a), or an approved application for investigational device exemption (IDE) under section 520(g).

The Electrotheraml Arthroscopy System™ is also 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 device was not provided to FDA as required by 21 CFR 807.81(a)(3)(ii), and the device was not found to be substantially equivalent to a predicate device.

Additionally, we also note that your web page titled, Spine: Physicians Workshops contains a schedule of upcoming didactic and hands-on training instruction to provide physicians clinical experience in using the SpineCATH™ device. We advise Oratec to limit the promotion of these demonstrations and didactic discussions to the intended use(s) for which you have received marketing clearance.

This letter is not intended to be an all-inclusive list of deficiencies associated with your ORA-50 RF Generator, SpineCath Intradiscal Catheter, TAC-S Family, and/or TAC-C probes. 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

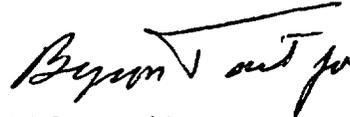
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the specific steps you have taken to correct the cited violations. Your response should also include all steps being taken to address misleading information currently in the market place and actions to prevent similar violations in the future. If corrective 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,

A handwritten signature in cursive script, appearing to read "Lillian J. Gill", with a horizontal line above it.

Lillian J. Gill  
Director  
Office of Compliance  
Center for Devices and  
Radiological Health

Enclosure

Guidance for Industry. General/Specific Intended Use