



2910 '00 MAR -7 A9:24 March 6, 2000

Mr. Lyle D. Jaffe  
Dockets Management Branch  
Department of Health & Human Services  
HFA - 305  
Food and Drug Administration  
Rockville, MD 20857

**Re: 00P- 0788 / CCP 1**

Dear Mr. Jaffe,

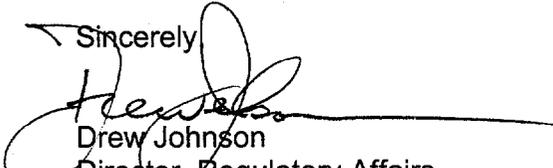
This letter is in response to a request from Dr. Kristen Bowsher, Scientific Reviewer, REDB to provide the Docket Management Branch with clean and complete copies of information and articles that were submitted with the ANS Reclassification Petition dated June 11, 1999. The ANS Totally Implanted Spinal Cord Stimulator for Pain Relief reclassification petition was officially received (filed) by FDA on June 16, 1999 although it was not assigned a docket file number until 02/29/00.

Enclosed are the best available copies of the articles requested and a copy of the typo corrected original cover letter as voluntarily resubmitted to FDA on August 2, 1999.

All copies are fairly legible and of sufficient quality to be reproduced and /or recorded by FDA.

Please let me know if I can be of further assistance.

Sincerely,

  
Drew Johnson  
Director, Regulatory Affairs

cc: Kristen Bowsher, Ph.D.  
Larry Pilot - McKenna & Cuneo, L.L.P.



August 2, 1999

2911 '00 MAR -7 A9:24

Ms. Janet Scudiero  
Food and Drug Administration  
Center for Devices and Radiological Health  
9200 Corporate Blvd (HFZ-410) Room 340G  
Rockville, MD 20850

**Re: Reclassification Petition for Totally Implanted Spinal Cord Stimulator  
for Pain Relief**

Dear Ms. Scudiero:

Per your request, enclosed are 20 copies (including a new informational summary of literature cited) of the Reclassification Petition for Totally Implanted Spinal Cord Stimulator for Pain Relief. I am also enclosing 20 additional copies of the summary of literature citing IPG's and RF systems that was sent to Ms. Kristen Bowsher a couple of weeks ago.

Please be advised that I have corrected a typographical error in the cover letter. The error was in the date of the Safe Medical Devices Act of 1990. (1970 instead of 1990).

Please let me know if I can be of further assistance.

Sincerely,

  
Drew Johnson  
Director, Regulatory Affairs



June 11, 1999

2912 '00 MAR -7 A9:24

Food and Drug Administration  
Center for Devices and Radiological Health  
Office of Standards and Regulations (HFZ-84)  
5600 Fishers Lane  
Rockville, Maryland 20857

**Re: Section 513(f) Reclassification Petition**

Dear Sir/Madam:

The undersigned submits the enclosed petition in accordance with Section 513(f) of the Federal Food, Drug, and Cosmetic Act, (the "FDCA"), 21 U.S.C. § 360c(f) and regulations appearing in 21 C.F.R. § 860.123 to reclassify the device "Totally implanted spinal cord stimulator for pain relief" from class III into class II.

Since 1978 the device "Implanted spinal cord stimulator for pain relief" as identified in 21 C.F.R. § 882.5880 has been classified into class II (performance standards). This classification was accomplished in accordance with procedures described in Section 513 of the FDCA. No performance standards have been identified for application to this device. Prior to and at the time of classification, the direct current generator power source for this device was external to the implanted portions of this device. Subsequently, implanted generators were developed. Because implanted generator devices for spinal cord stimulators were not introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, Section 513(f) of the FDCA required classification into class III (premarket approval).

The only difference between "Implanted" and "Totally implanted" spinal cord stimulator devices is the location of the generator power source. Therefore, the petitioner believes that reasonable assurance of safety and effectiveness can be maintained through the application of special controls as authorized for class II devices since passage of the Safe Medical Devices Act of 1990.

The attached document is formatted in numerical order to address the specific reclassification content and form requirements outlined in 21 C.F.R. § 860.123.

Sincerely,

A handwritten signature in black ink, appearing to read "Drew Johnson", is written over a large, stylized flourish.

Drew Johnson  
Director, Regulatory Affairs  
Advanced Neuromodulation Systems, Inc.

From: ANS (972)309-8000  
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PLANO, TX, 75024

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HFA - 305 FDA  
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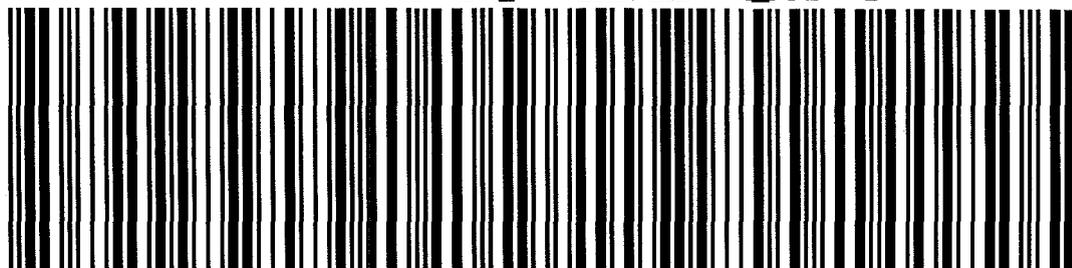
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