



June 11, 1999

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

1827 00 FEB 29 1999

**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 1970.

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,

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