



COMPREHENSIVE PAIN & REHABILITATION

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September 25, 2000

Documents Management Branch (HFA-305)
Food and Drug Administration
5630 Fisher Lane, Room 1061
Rockville, Maryland 20852

Re: Docket #00P-0788 & #00D-1455

To Whom It May Concern:

This letter is being submitted in response to the FDA's request for comments relative to the recent Federal Register publication of the Notice of Panel Recommendation to reclassify the Totally Implanted Spinal Cord Stimulator for Pain Relief.

I have ten years of experience in interventional techniques of pain medicine which includes implantation of the radiofrequency and internal pulse generator type spinal cord stimulation device. The recent Notice of Panel Recommendation to reclassify the internal pulse generator device from a class III to a class II status is entirely appropriate based on the safety and efficacy of this device. It is my opinion that this move of reclassification will significantly stimulate innovative competition within the market place which will result in development of even more efficacious implantable technologies for the relief of chronic pain in the patients whom I treat.

The FDA panel is to be commended for their efforts to reclassify the internal pulse generator device to a class II status as I believe this is a reclassification that has long been overdue.

If there is any way that I can be of any assistance to the FDA regarding its decision on this matter of reclassification, please do not hesitate to contact me.

Cordially,

Thomas L. Yearwood, M.D., Ph.D.
TLY/bl

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