



**Alabama Pain Center**

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September 22, 2000

Documents Management Branch (HFA - 305)  
Food and Drug Administration  
5630 Fisher Lane Rm. 1061  
Rockville, MD 20852

RE: Docket No. OOP- 0788 and OOD-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 15 years of experience implanting both Radio Frequency and IPG type spinal cord stimulation devices. It is my belief that the FDA notice of panel recommendation and special control guidance document adequately addresses the concerns regarding the assurance of safety and effectiveness for the IPG device for pain relief. The risk to health of lead migration, device failure, tissue reaction, skin erosion, surgical, procedural risk, EMC and MR compatibility concerns are appropriately identified and characterized by the FDA and their panel.

I believe that the Special Control Guidance for Premarket Notification for Totally Implanted Spinal Cord Stimulators for Pain Relief covers the elements necessary to allow the medical device industry to design and manufacture safe and effective IPG's for pain relief. This guidance will be useful to both industry and the FDA to provide equivalent assurance of safety and effectiveness when premarket notifications are submitted to the FDA for these types of devices. The proposed labeling, technological reporting, device testing and manufacturing requirements are consistent with what I believe to be necessary to address the design and manufacturing concerns for this type of device.

I commend ANS and the FDA for their efforts to reclassify the IPG device to a Class 11 status. Over regulation of this device has long been overlooked. This is definitely a step in the right direction by the FDA to reduce the burden and speed the process of getting new IPG's to market. Competition breeds innovation, and I believe that this reclassification will ultimately help to speed the innovation that is still needed to improve the lives of the chronic pain patients whom I treat.

Sincerely,

K. Dean Willis, MD

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**K. Dean Willis, M.D.**

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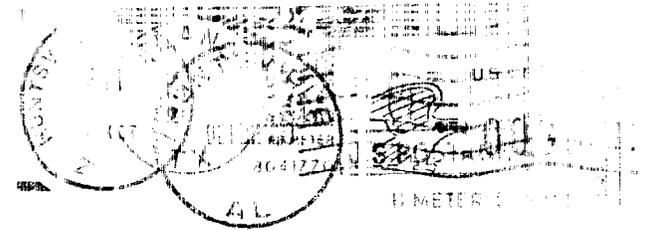
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