

# MUSC

## NEUROSURGERY SERVICES

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October 4, 2000

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Dockets Management Branch (HFA-305)  
U.S. Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

Dear Sir/Madam:

I recently became informed of the FDA's intention to potentially reclassify implantable spinal cord stimulators from a class III to class II device. I would like to add my opposition to this move as I think it may result in serious consequences regarding patient safety.

As you are undoubtedly well aware, spinal cord stimulator devices may be extremely complex. In fact, the devices can be as complex as some of the procedures that are required to implant them and maintain them on a chronic basis. I am deeply concerned that the FDA's reclassification of this type of implant to a class II device may result in inferior products being brought to market that at the very least would be flawed and ineffective and at the worst could potentially cause serious patient harm. I bring this up since a large portion of my practice is devoted to treatment of patients with chronic pain and as such I implant a substantial number of spinal cord stimulator devices on an annual basis.

In summary, I unequivocally believe that reclassifying these devices will compromise the integrity of this type of therapy and may seriously jeopardize patients for whom this therapy may be applied. Furthermore, I believe the FDA classification of level III along with the corresponding premarket approval is imperative to protecting safety of patients who are implanted with these systems.

00D-1455  
00P-0788

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Thank you very much for your consideration of my comments, if you have any further questions please do not hesitate to contact me at 843-792-5650.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard K. Osenbach". The signature is fluid and cursive, with a long horizontal line extending to the right.

Richard K. Osenbach, M.D.  
Assistant Professor  
Department of Neurological Surgery  
MUSC

RKO/kl

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