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October 2, 2000

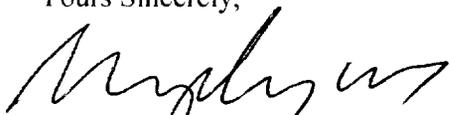
Dockets Management Branch (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

To Whom It May Concern:

I am writing as a Pain Medicine specialist to inform you of my concern as to the FDA's intention to reclassify spinal cord stimulators (SCS) from class III to class II. I have been implanting spinal cord stimulators for many years and have found them to be complex devices that have become more complex over the last several years with advanced circuitry and varying power sources. These devices, as you know, are totally implantable with leads surgically placed into the epidural space and over the posterior aspect of the spinal cord. The procedure to implant them involves specific knowledge of the spinal cord anatomy, subspecialty training for placement of needles in and about the spinal cord and the nerve roots, and surgical training for appropriate implantation of the power device. Such a move would eliminate some critical checks and balances that help promote patient safety.

I am concerned that the potential reclassification of this device to class II would allow variability in the standards of the product that comes to market and could potentially endanger the lives of patients. As a physician that treats chronic pain patients, I am concerned for their safety as well as the integrity of my practice and those that practice Pain Medicine. It is critical to have manufacturing checks for any potential manufacturer of these devices. I believe that reclassification of these devices compromises the integrity of this class of pain relieving equipment. The FDA classification level III with the corresponding pre-market approval is imperative to protecting the safety of patients receiving these complex and scientifically advanced devices. I appreciate your close attention and consideration of my opinion. If I can be of further help or provide further information, you may contact me at my office at (210) 805-9800 or on my cell phone at (210) 269-8400.

Yours Sincerely,



C. William Murphy, M.D.

CWM/svk

cc: Michael Murphy, M.D.
cc: Donald Bacon, M.D.
cc: Raul Martinez, M.D.
cc: Stephanie Jones, M.D.

dd: 10/02/00

dt: 10/03/00

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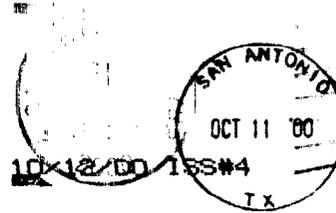
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CPM

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