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November 1, 2000

DEPARTMENT OF ANESTHESIOLOGY

DAVID A. BRYCE, M.D.
INTERVENTIONAL PAIN MANAGEMENT CLINIC

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

Dear Sir:

I am writing an opposition to the FDA's intention to reclassify Totally Implantable Spinal Cord Stimulators (SCS) from Class III to Class II, a move to eliminate critical checks and balances that help promote patient safety.

Spinal cord stimulator devices are extremely complex. They involve highly intricate and specialized circuitry in a power source that are totally implantable with leads surgically placed into the spinal area. The devices themselves are involved complex circuitry and it is very important that proper checks and balances be done on this equipment.

As you know, reclassification with device to Class II potentially allows a lower standard product onto the market, which could be potentially dangerous to patients. I see patients on a regular basis and use spinal cord stimulation, and it is part of my practice. I am concerned for their safety, as well as the integrity of my practice.

Since the implantable spinal cord stimulator devices are already approved by the FDA, not all safety features are well understood. It is very important to have manufacturing checks of any potential problems that could arise.

In 1995, the FDA stated that these devices are "potentially high risk".

I firmly believe that the reclassification of these devices may compromise integrity through the entire Class of devices which may subsequently jeopardize future patients, and it may enforce withdrawal of therapy that could help them. FDA Class III with corresponding pre-market approval is impaired with protecting the safety of these patients or seeing the technologically advanced devices.

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Dockets Management Branch
November 1, 2000
Page 2

Thank you for your consideration in reading this letter.
Please do not hesitate to contact me if I can provide you with
any additional information.

Sincerely,

A handwritten signature in cursive script, appearing to read "DAB", is positioned above the typed name.

David A. Bryce, M.D.
Pay Management Services
Marshfield Clinic

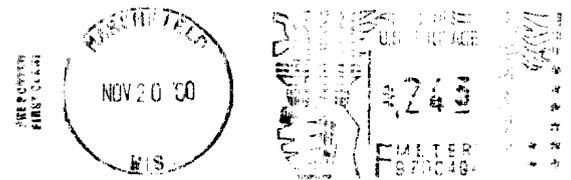
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1000 N OAK AVE
MARSHFIELD WI 54449-5777

FORWARDING SERVICE REQUESTED



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5630 FISHERS LANE ROOM 1061
ROCKVILLE MD 20852

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