



DEPARTMENT OF NEUROSURGERY
Henry Ford Hospital & Medical Centers

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October 2, 2000

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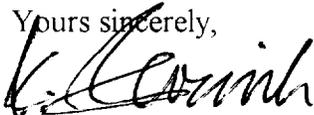
Dockets Management Branch (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

TO WHOM IT MAY CONCERN:

Midwest Neuro-Oncology Center
Cerebrovascular Surgery
Skull Base Surgery
Epilepsy Surgery
Pain & Movement Disorders
Stereotactic Surgery
Surgery for Spinal Disorders
Brain & Spinal Cord Injury
Pediatric Neurosurgery

The decision of the FDA to reclassify "Totally Implantable Spinal Cord Stimulators" from Class III to Class II creates a concern regarding the necessary controls that are required in the manufacture of these products. These items in the past have been identified by the FDA as "potentially high-risk" and deserve due consideration in the maintenance of stricter guidelines regarding the manufacturer of them.

Our Pain Service within Henry Ford Hospital sees numerous patients who are candidates for the implantation of spinal cord stimulators. Because of the rather highly technical nature of this device I would caution the FDA to maintain the same scrutiny that it has exerted in the past regarding this sort of instrumentation. My concern is in regards to the standard of care that is to be achieved nationally in regards to the management of pain, particularly as it pertains to lower back and leg pain, primarily but also in regards to a myriad of other neurogenic pain syndromes.

Yours sincerely,

Kost Elisevich, M.D., Ph.D.
Department of Neurosurgery

KE/cp



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HENRY FORD HOSPITAL

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*** OCT-04-00 ***

RESORTS
FIRST CLASS



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