



Medtronic

Medtronic Neurological
800 53rd Avenue NE
Minneapolis, MN 55421.1200 USA
www.medtronic.com

tel 612.514.5000
tel 800.328.0810 toll-free
fax 612.514.5229

0617 '00 SEP 26 A9:16

September 25, 2000

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

**RE: Docket No. 00D-1455; Guidance for Industry; Special Control
Guidance for Premarket Notifications for Totally Implanted Spinal
Cord Stimulator for Pain Relief**

Dear Dr. Pagano:

On behalf of Medtronic, I am requesting a 90-day extension to the public comment period after the final order is published. We feel it is inappropriate to comment on a guidance document during the same time period as the associated proposed rule for down classification. Since Medtronic has chosen to oppose the down classification, we request further comment after the order becomes final, assuming the Totally Implanted Spinal Cord Stimulator is down classified.

Furthermore, the proposed guidance is totally inadequate in its current state, especially in light of patient safety. I am therefore reiterating the need for a 90-day extension to the public comment period after the final order is published, so that we may effectively prepare comments. The current public comment period ends on October 6, 2000. I respectfully request that this document become a part of the administrative record.

Thank you for your consideration.

Sincerely,
Medtronic Neurological



Lynn Switzer

Director of Regulatory and Clinical

ph.: 763-514-7338
fax: 763-514-7285
e-mail: lynn.switzer@medtronic.com

cc: Philip Phillips, FDA
Celia Witten, FDA

00D-1455

EXT 1

When Life Depends on Medical Technology

From: MARY WARREN (612)514-7464
MEDTRONIC, INC
800 53RD AVE. N

SHIPPER'S FEDEX ACCOUNT #



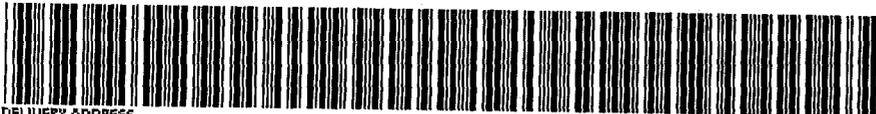
MINNEAPOLIS, MN, 55421

To: Dockets Management Branch (HFA-305) (301)443-8818
Docket No. 00D-1455

SHIP DATE: 25SEP00
WEIGHT: 1 LBS

US Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD, 20852

Ref:



DELIVERY ADDRESS

TRK # 7918 5781 5190 FORM 0201

PRIORITY OVERNIGHT

IAD

20852-MD-US

XA GAIA

TUE

AA

Deliver by:
26SEP00

