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Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

PURGED *RFK*

November 23, 1998

[Handwritten signature]
cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 99 - 04

William W. George
Chairman of the Board and
Chief Executive Officer
Medtronic, Inc.
7000 Central Avenue NE
Minneapolis, Minnesota 55432

Dear Mr. George:

During an inspection of your Neurological Division at 800 - 53rd Avenue NE, Columbia Heights, MN, that concluded on September 3, 1998, Food and Drug Administration (FDA) Investigator Philips determined your firm manufactures the Activa™ Tremor Control System. These tremor control systems are devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The inspection revealed that this device is adulterated within the meaning of Section 501(f)(1)(B) of the Act in that a PMA supplement was not submitted and approved by FDA as required by Title 21, Code of Federal Regulations, Part 814.39 (21 CFR 814.39) and Section 515 of the Act, before labeling changes affecting the safety or effectiveness of the device were made. Medtronic revised the labeling of the Activa™ device by preparing an "Implant Technique Guide" that included an alternative surgical placement for the device, and changed the "Indication" and "Use in Specific Populations" sections of the approved labeling. For example: the "Indications" section of the "Implant Technique Guide" does not

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reflect that the device is approved for "*Unilateral thalamic stimulation*" in patients "*not adequately controlled by medications and where the tremor constitutes a significant functional disability*"; and the statement, "*The safety or effectiveness of this therapy has not been established for...bilateral stimulation,*" which appears in the "Use in Specific Populations" section of the approved labeling, is not included in the "Implant Technique Guide."

We also noted that paragraph 2.2.3 "Number of Leads" in "PRODUCT SPEC - DBS/QUAD LEAD, 3387. NUMBER 084999. REV K" indicates that the burr hole cap is designed to accommodate either one or two leads. The Activa™ device is only approved for use with one lead, and a change to the design specifications of this component to allow the use of two leads affects the safety or effectiveness of the device and requires an approved PMA supplement. Your response should provide a detailed explanation of this apparent change in the design specifications of the approved device and information on the distribution and use of burr hole caps designed to accommodate one or two leads.

This letter is not intended to be an all-inclusive list of the deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems you must promptly initiate permanent corrective actions. Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory actions being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations including an explanation of each step being taken to identify and make corrections to any

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underlying systems problems necessary to ensure that similar violations will not reoccur. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to Compliance Officer Thomas P. Nelson at the address indicated on the letterhead.

Sincerely,

A handwritten signature in cursive script, appearing to read "Edwin S. Dee".

Edwin S. Dee
Acting Director
Minneapolis District

TPN/ccl