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December 1, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fisher Lane Room 1061
Rockville, MD 20852

Re: FDA Docket Number: 00P-0788

To Whom It May Concern:

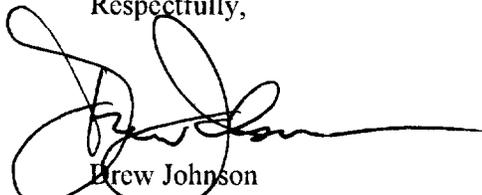
Advanced Neuromodulation Systems, Inc. (ANS) is providing these comments in response to the October 19, 2000 submission by Hale and Dorr, L.L.P. of certain documents as part of the administrative record.

It is our understanding that all documents, including computer stored data and audio/video recordings, relating to the petition for reclassification filed on June 16, 1999 and referenced in the docket number cited above are part of the administrative record, irrespective of whether filed in response to the September 6, 2000 Federal Register ("F.R.") Notice. Therefore, there is no need to add volumes of repetitive documents to the existing administrative file through the above referenced Docket Number. The publication of the F.R. Notice on page 54053 of the F.R. was for a specific purpose as part of the entire administrative record and did not require either the Food and Drug Administration ("FDA") or interested parties to resubmit each and every related document already maintained in the administrative file.

Nonetheless, the Hale And Dorr, L.L.P. cover letter contains two errors which justify correction on the public record. First, the January 31, 2000 reference to "Medtronic's Petition for Reclassification. . ." is incorrect. Medtronic, to the best knowledge of the undersigned, has not submitted any petition. Second, in the reference to the copy of the EN4550.2-1 omitting every other page, the FDA was provided with a complete copy. If the administrative file does not contain the complete copy, the undersigned offers to provide another copy at the request of the FDA. In addition, Medtronic has repeatedly failed to include the attached letter, which appears as an enclosure to the often referenced December 29, 1995 letter from Susan Alpert, Ph.D., M.D.

In summary, it is the understanding of ANS that the administrative record includes documents other than those maintained in response to the September 6, 2000 F.R. Notice. If this understanding is not correct, the courtesy of a clarification will be appreciated.

Respectfully,


Drew Johnson
Director, Regulatory Affairs

cc: J. Sheehan

00P-0788

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 29 1995

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Robert J. Klepinski
Senior Legal Counsel
Medtronic, Inc.
Law Department
7000 Central Avenue, NE
Minneapolis, Minnesota 55432-3576

Re: C950010 -- Classification of Medtronic Itriel™
Dated: November 22, 1995
Received: December 20, 1995

Dear Mr. Klepinski:

This is response to your request to Mr. Fred Sadler for classification information dated November 22, 1995. The Medtronic Itriel™ Totally Implantable Spinal Cord System was determined by PDA to be a class III device by order dated October 29, 1980, (copy enclosed). The Food and Drug Administration (FDA) determined that the Medtronic Totally Implantable Spinal Cord System was not substantially equivalent to any device marketed prior to May 28, 1976, or to any device classified as a class I or class II device; therefore it could not be marketed until FDA approved a premarket approval application in accordance with Section 513(f) of the Federal Food, Drug, and Cosmetic Act.

As specified by Section 513(f) of the Food, Drug, and Cosmetic Act (act), a device to be marketed after May 28, 1976, is classified into class III unless the FDA determines the device to be substantially equivalent to a preamendments device, or the device is reclassified into class I or class II.

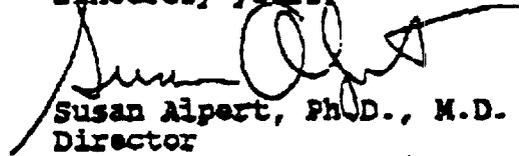
FDA determined that this Medtronic device was not substantially equivalent to devices classified in Title 21, Code of Federal Regulations, Section 882.5880 (21 CFR 882.5880) based on significant technological differences. For example, the Medtronic device employs an implanted device containing a power source; whereas, the devices classified in 21 CFR 882.5880 employs an implanted device comprised entirely of passive components with necessary energy being provided by an external device.

As further evidence of this determination, FDA sent to Medtronic, Inc. on August 2, 1989, an order approving the Premarket Approval Application (PMA) for the Medtronic Itriel II™, which includes a Model 7424 Implantable Pulse Generator and a Model 7496 Quadrapolar Extension.

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We believe this unequivocally establishes that Medtronic Totally Implantable Spinal Cord System is by statute a class III device for which an approved PMA is required for marketing. If you have further questions, please contact Robert F. Munzner, Ph.D., at (301) 443-8517.

Sincerely yours,



Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

From: LINDA BRIGGS (972)309-8023
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SHIPPER'S FEDEX ACCOUNT #



To: Document Management Branch (HFA-305 (301)594-1296
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Rockville, MD, 20852

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