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

Re: Docket No. 00D-1455: Draft Guidance for Industry; Special Control Guidance for
Premarket Notifications for Totally Implanted Spinal Cord Stimulators for Pain Relief

This letter is in response to the FDA's request for public comment regarding the draft guidance for industry entitled "Special Control Guidance for Premarket Notifications for Totally Implanted Spinal Cord Stimulators for Pain Relief." Thank you for extending our comment period to November 3, 2000, as indicated in the letter we received from Linda Kahan. As we have stated previously, the original 30-day deadline for submitting comments regarding the draft guidance document is significantly shorter than the norm and did not allow sufficient time to provide meaningful feedback. Medtronic objects to reviewing this document prior to the rule being finalized let alone the brevity of the time period for review of a guidance document of this nature.

Given the complexities of a totally implanted spinal cord stimulator (SCS), we believe that the draft guidance document is grossly inadequate and will fail to protect public safety, which is an integral part of our corporate mission. This letter will focus on only a few of the most significant deficiencies we have identified: electromagnetic compatibility, net direct current, pulse stability, battery-related issues, and overall device reliability.

electromagnetic compatibility

The standard cited in the draft guidance document (IEC 601-1-2) is inadequate for implanted devices for several reasons. First, the standard sets a minimum immunity level of 3 volts per meter (V/m) in the 26 to 1,000 MHz frequency range, however, techniques such as shielding, grounding and filtering can protect devices from electromagnetic fields that are much more intense than the 3 V/m level specified. Second, the standard does not address electromagnetic interference from sources with very low carrier frequencies (e.g., AC power line fields) or transient fields (e.g., pulsed gradient fields from magnetic resonance imaging systems, where most of the frequency content falls below the range

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specified in the standard). Third, the standard doesn't directly address electrosurgical cautery, theft detectors, defibrillators, or cell phones, all of which may interfere with normal device operation.

net direct current

Although net direct current (DC) should be minimized, since it can cause hardware corrosion and potential nerve tissue damage, the guidance document does not define a safe upper limit. All stimulation operating modes (e.g., steady state and cycling) must be evaluated for net DC. In addition to specifying an acceptable upper limit, the guidance document should also include test methodology for evaluating whether output stimulation pulses meet the specification. Furthermore, loads must be specified, and a manufacturer must be able to characterize how the net DC generated affects specific materials within the device.

output stability

In the draft guidance document, pulse stability is tested only with respect to resistive load. Pulse stability should also be tested with respect to battery voltage, battery impedance, telemetry, saline load, and programmed voltage.

battery-related issues

The presence of an implanted power source is the most important safety-related characteristic of a totally implanted SCS, significantly differentiating it from an SCS with an external power source. However, the only references to the battery in the draft guidance document include 1) suggested labeling (i.e., a chart illustrating the estimated battery life of the device at various output usages, a statement regarding the fact that battery failure can result in ineffective pain control, and a warning addressing burns that may result if the generator case is ruptured or pierced), 2) a specification pertaining to the elective replacement indicator (i.e. the interval between indicator activation and actual end of life of the device), 3) design verification testing, which is described very vaguely (i.e., "should be appropriate for the component and include appropriate operational, environmental, and reliability tests with tolerances and limits compatible with the entire system's specifications"), and 4) a statement that "[a]ll stimulation parameters and all features must be characterized for functioning under expected . . . battery voltage's lifetime."

Other issues that should be addressed include 1) power-on reset (i.e., evaluation of whether the power-on reset circuit operates safely), 2) environmental testing

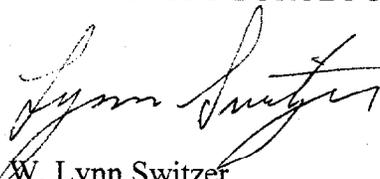
(e.g., the effect of mechanical shock, vibration, and temperature on shorting or leaking), 3) feed-through hermeticity, 4) battery discharge characterization, and 5) short testing (i.e., evaluation of whether battery meets specification for response to a short circuit). In addition, as referenced in the label warning, battery hermeticity should also be evaluated since leakage can result in serious injury.

overall device reliability

The draft guidance document includes no discussion of overall device reliability or reliability analysis. At the least, the guidance document should address testing to ensure that single fault failure modes do not result in a hazardous condition, as well as specifications regarding the telemetry protocol (i.e., the maximum amount of time it should take to turn the device off in an emergency situation).

In conclusion, we would like to reiterate that the issues listed above are only a small subset of the shortcomings that Medtronic has identified with respect to the draft guidance document. We welcome the opportunity to work with FDA to address our concerns, however, we believe that even the most comprehensive guidance document will not be sufficient to protect patient safety, because of the many safety-related issues that can only be identified and addressed via clinical trials (e.g., EMC, MRI, pocket erosion, surgical technique, and other such outside influences). We therefore urge FDA to withdraw the draft guidance document and reevaluate its position regarding reclassification of the totally implanted SCS from a class III to a class II device.

Sincerely,
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