



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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James Dennison
Vice President, Regulatory Affairs
Medtronic Physio-Control Corp.
11811 Willows Road NE
P.O. Box 97006
Redmond, Washington 98073-9706

Re: Docket No. 199N-0418

We have received your letter dated January 26, 2004, commenting on the reclassification of Automatic External Defibrillators. In order for FDA to make a decision regarding reclassification, we request additional information from you.

1. FDA believes that the results from ease of use testing could ensure that a defined level of human factors standards has been met. To include this in a special controls guidance document, FDA will need to more fully define the scope of such usability testing. Please comment on the need for usability testing, particularly as these devices may now be considered for over-the-counter status. Please comment on what aspects of usability are considered the most critical. Please offer a proposal for how to appropriately conduct these studies in terms of methodology, sample size, and pass/fail criteria.
2. In order to create a special controls guidance document, it is necessary to identify all the risks associated with a device and the ways in which special controls can be used to mitigate those risks. Please provide your assessment of the risks associated with the use of AEDs, and the special controls that can be used to mitigate them. Please comment on whether the over-the-counter status of these devices raises new risks, and if so how they would be mitigated by special controls.
3. Facility inspection is one general control that FDA has over quality manufacturing. A Class II 510(k) device does not require premarket review of Quality System information, does not require pre-approval inspections and may potentially be inspected with less frequency than a Class III PMA device. Recent recall history in this product area suggests problems in manufacturing and post-clearance design changes. Please comment on the differences between the two classes and justify why pre approval review and inspections would not be necessary to control risks.

94N-0418

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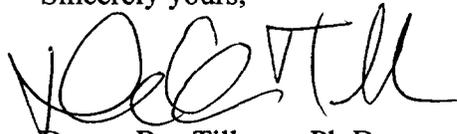
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To respond to this request, please refer to the Docket Number, above, and submit your comments within 30 days from the date on this letter to:

Dockets Management Branch
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

If you have additional questions, please contact Oscar Tovar, MD, (301) 443-8609 extension 156.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Donna-Bea Tillman". The signature is fluid and cursive, with the first name "Donna" being the most prominent.

Donna-Bea Tillman, Ph.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health