



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

JUL 23 2004

Tish Treherne  
Philips Medical Center  
2301 Fifth Avenue  
Suite 200  
Seattle, WA 98121 - 1825

Dear Ms. Treherne,

Re: Docket No. 2004P-0164

This is an interim response to the petition you filed with the Food and Drug Administration (FDA) on April 6, 2004, requesting an exemption from the medical device tracking requirements for the Heartsteam automated external defibrillators.

Because of competing priorities, we have not yet completed our review of your petition and are unable to give you a final response at this time. We expect to issue a final response in the near future.

If you have any questions about this interim response, please call Myrna Hanna at (301) 827-2971.

Sincerely yours,

Timothy A. Ulatowski  
Director  
Office of Compliance  
Center for Devices and  
Radiological Health

2004P-0164

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