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May 6, 2004

Dockets Number 95S-0158  
Dockets Management Branch (HFA-305)  
Food and Drug Administration  
1242 Parklawn Drive, Room 1-23  
Rockville, MD 20857

Re: Yearly Report, 2004  
IDE #G980067  
Automated External Defibrillators – Public Access Defibrillation (PAD)  
Indications for use: victims of sudden cardiac arrest  
Sponsor/Contact Person H. Leon Greene, M.D.  
PAD Clinical Trial Center  
1107 NE 45<sup>th</sup> Street, Suite 505  
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Ladies and Gentlemen:

The Public Access Defibrillation (PAD) Trial has completed its study. It was funded by the National Heart, Lung, and Blood Institute, the American Heart Association, Guidant Corporation, Medtronic/Physio-Control Corporation, Philips Corporation/Heartstream Operation, Laerdal Corporation, and Cardiac Science/Survivalink Corporation. It began on October 1, 1999. Data collection ended with events occurring before September 30, 2003. The study followed the investigational plan as submitted.

The study results were presented at the American Heart Association Annual Scientific Sessions in November, 2003. The primary results paper has been submitted to the New England Journal of Medicine.

In summary:

- 993 units participated.
- Training involved nearly 20,000 volunteers.
- Automated external defibrillators were placed at all units randomized to CPR+AED.
- No serious unexpected adverse events occurred.
- The survival rates were doubled in the CPR+AED units.

The public disclosure plans implemented by each of the sites are enclosed.

One paper has been published since our last report. It is enclosed.

Please accept this document as the Yearly Report and Closeout Report for IDE #G980067.

Sincerely,

H. Leon Greene, M.D.

Enclosures: List of investigators and sites  
Disclosure plans from each of the clinical sites  
Reprint

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Public Access Defibrillation