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June 5, 2003

IDE Document Mail Center (HFZ-401)
FDA, CDRH
9200 Corporate Boulevard
Rockville, MD 20850

Re: Yearly Report, 2003
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.
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Ladies and Gentlemen:

The Public Access Defibrillation (PAD) Trial is ongoing and 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, and data collection will continue on events occurring through September 30, 2003. The study continues to follow the investigational plan.

The Data and Safety Monitoring Board (DSMB) met on May 15, 2003, and recommended continuation of the study.

In summary:

- 993 units are participating.
- Training has been completed for nearly 20,000 volunteers.
- Automated external defibrillators have been placed at all units randomized to CPR+AED.
- Episode data are accumulating.
- No serious unexpected adverse events have occurred.

A copy of the only article published to date is enclosed.
Data collected to date do not yet allow conclusions to be drawn from the study.
Please accept this document as the Yearly Report for IDE #G980067.

Sincerely,

H. Leon Greene, M.D.

Enclosures: List of investigators and sites
Reprint

955-0158

RPT 11

Public Access Defibrillation

PAD Investigators by Site Name

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