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January 2, 2003

Re: IDE #G980067
Automated External Defibrillator (PAD-I)

Paul A. Williams, B.S.E.
Investigational Device Exemption Program
Office of Device Evaluation
Center of Devices and Radiological Health
IDE Document Mail Center (HFZ-401)
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Dear Mr. Williams:

Enclosed in triplicate are the documents you requested for the demonstration of public disclosure to communities for the PAD Trial. These items are grouped by individual site, and include the original IRB submission and approval.

A preliminary summary of the material is also attached as a draft of a paper (including Tables), outlining the methods used by the sites to disclose their activities to the communities. This manuscript draft is a work in progress and is subject to revision.

Also attached are the most recent Data and Safety Monitoring Board minutes and the NHLBI summary of the most recent meeting, at which the Board recommended that the study be extended to September 30, 2003.

A copy of this material has also been sent to the Dockets Management Branch, as you requested.

Please let us know if you need any further material. We plan to submit the information used to disclose the results of the study to communities when it has been completed.

Sincerely,

H. Leon Greene, M.D.

955-0158 RPT 8

Public Access Defibrillation