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January 16, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Subject: Request for FDA Reclassification of AEDs from Class III to Class II

Dear Sirs:

Based upon personal application of AED devices within our institution and in the prehospital setting as part of the National Heart Lung & Blood Institute's Public Access to Defibrillation (PAD) Trial, I wish to speak in favor of reclassification of the AEDs from Class III to Class II devices. During the PAD Trial, we found no harm from use of the device by hundreds of trained lay rescuers. Other EMS systems have experience with these devices being used safely by trained EMTs for over a decade. Not only are the devices safe, but they have been demonstrated to be as effective as existing manually operated defibrillators in treating ventricular fibrillation. They work on essentially the same principle as existing manual defibrillators with the exception that rhythm recognition software supports the clinical decision to activate the device. This clinical decision support software has been demonstrated to be robust and efficient in multiple preclinical and clinical trials.

Knowing the clinical benefit possible with a wider use of AED devices, it would be very harmful to the public to impose additional barriers to distribution at this time as would arise from a mandate for AED manufacturers to provide further safety research as would required prior to marketing these devices under a Class III device designation.

By way of disclosure, I wish to note that I have no financial interest in AED manufacturing or distribution companies, nor have I received (currently or previously been) AED research support outside of supplies made available by the manufacturers for the purpose of completion of the PAD trial.

Sincerely,

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