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Docket No. 199N-0418 Comments

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HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Reference: Docket No. 199N-0418
Medical Devices: Reclassification of Automated External Defibrillators
Federal Register Vol. 68, No. 208
Dated October 28, 2003

To whom this may concern:

The following is submitted in response to the above Federal Register notice requesting interested parties to provide new information related to reclassifying automated external defibrillators into class II. (Currently automated external defibrillators are classified as class III, preamendment devices.) As a manufacturer of automated external defibrillators, Philips Medical Systems has two comments:

1. We support the reclassification designation into class II. Since the passage of the Federal Food, Drug and Cosmetic Act of May 28, 1976, automated external defibrillator (AED) technology has evolved into self-contained, light-weight, easily portable, reliable devices that can be successfully used by persons without formal, routine medical training. This is a very large step from the early 1960's Mine Safety Appliance Co. device that weighed over 45 lbs and did not have a self-contained power supply to deliver a 200 joule shock. Furthermore, low energy manual defibrillators (delivers less than 360 joules), that require users to read the electrocardiogram (ECG) and diagnose the condition, are already classified as class II devices (21 CFR 870.5300, product code LDD). AED decision algorithm technology was on the market before the Medical Device Amendments,¹ has over twenty years history of regulatory oversight² and has

¹ HeartAid 60 by Cardiac Resuscitation Corporation, a fully automated external defibrillator.



advanced to a performance level where placing automated defibrillators in a higher regulatory classification category, when no medical decision regarding shock delivery is necessary by the user, is no longer appropriate and constitutes over-regulation.

2. We recommend that, in parallel with the reclassification action, the Agency issue a Special Controls Guidance Document on automated external defibrillators. The recently issued FDA “Special Controls Guidance Document: Arrhythmia Detector and Alarm” (October 28, 2003) identifies many of the same technological information and safety testing that apply to automated external defibrillators. The special control guidance document describing the content of premarket submissions for AEDs should also include:
 - a. A description and comparison of the waveform, decision algorithm, classification of rhythms and artifact detection mechanisms between the new device and predicate. A block diagram of the hardware/software interfaces should also be provided for consistency during Agency review.
 - b. Results from recommended bench top, animal and clinical testing (as appropriate) for the performance of the waveform, decision algorithm and artifact detection systems. Standards for testing and reporting defibrillator technical performance, such as IEC 60601-2-4, AAMI DF:80³ and an AHA publication,⁴ should also be considered when developing the special guidance document such that the Agency and users can more easily compare and contrast these important AED capabilities. To that end, these standards should also be considered for formal recognition by the FDA and relied upon in the guidance document.
 - c. A description and comparison of the self-tests performed by the AED between the new device and predicate. All AEDs currently on the market in the United States perform automated self-tests, but because of implementation differences that could affect safety and effectiveness, this information should be provided in detail to the Agency such that it can make a substantial equivalence determination.

² Examples of previously cleared AEDs include Cardiac Resuscitation Corporation, HeartAid Model 80, K820609, cleared 8/6/1982; Physio-Control Personal Defibrillator, #K832833, cleared 10/26/1984.

³ This is the new draft standard that combines and updates AAMI DF:2 and AAMI DF:39.

⁴ Kerber, R. et al. Automatic External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms and Enhancing Safety. *Circulation*. 1997; 95:1677-1682.



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- d. Results from ease of use testing. As the evolution of AED technology has occurred, a corresponding expansion has resulted in the AED user group consisting of first responders who are not medical professionals and often have no training with the device. The increasing widespread presence of this group places a burden of responsibility on AED manufacturers to design user interfaces that can be operated safely and effectively by non-professionals. User interface validation tests should show that a defined level of human factors standards have been met, using a sufficient powered representative user population. Test results should be included in the FDA submission.

We appreciate the opportunity to provide these comments in support of the petition to reclassify automated external defibrillators into class II. Please feel free to contact me at tamara.yount@philips.com or 206.664.5141.

Sincerely yours,

A handwritten signature in cursive script that reads "Tamara Yount".

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