

DMB

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

Display Date 3-5-04  
Publication Date 3-8-04  
Certifier G. P. Kelly

[Docket Nos. 1994N-0418 and 1996P-0276]

**Medical Devices: Cardiovascular Devices: Reclassification of the Arrhythmia Detector and Alarm; Correction**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; correction.

---

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a final rule that appeared in the **Federal Register** of October 28, 2003 (68 FR 61342). That document issued a final rule reclassifying arrhythmia detector and alarm devices from class III to class II (special controls). This device is used to monitor an electrocardiogram (ECG) and to produce a visible or audible signal or alarm when an atria or ventricular arrhythmia occurs. The document published with an inadvertent error. This document corrects that error.

**DATES:** *[Insert date of publication in the Federal Register.]*

**FOR FURTHER INFORMATION CONTACT:** Elias Mallis, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-441-8571, ext. 177.

**SUPPLEMENTARY INFORMATION:** In FR Doc. 03-27115, appearing on page 61342 in the **Federal Register** of Tuesday, October 28, 2003, the following correction is made:

§ 870.5310 [Corrected]

On page 61344, in the first column, in § 870.5310 *Automated external defibrillator*, beginning in the seventh line, the parenthetical “(restoring normal hearth rhythm)” is corrected to read “(restoring normal heart rhythm).”

Dated: 2/26/04

February 26, 2004.

Beverly Chernaik Rothstein

Beverly Chernaik Rothstein,  
Acting Deputy Director for Policy and Regulations,  
Center for Devices and Radiological Health.

LB  
3/1/04

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

BILLING CODE 4160-01-S

CERTIFIED COPY OF A TRUE ORIGINAL

Gloria Tenley