



U.S. Department of Health and Human Services

Food and Drug Administration

## **RECALLS AND FIELD CORRECTIONS: DEVICES -- CLASS II**

### **AED Plus Defibrillator, ZOLL MEDICAL CORP.**

Source: FDA Enforcement Report February 19, 2003

<http://www.fda.gov/bbs/topics/enforce/2003/ENF00783.html>

#### **PRODUCT**

Zoll AED Plus Defibrillator (Automatic External Defibrillator). Recall # Z-0548-03.

#### **CODE**

Serial Numbers: X02F000812 through X02K007486.

#### **RECALLING FIRM/MANUFACTURER**

Zoll Medical Corp., Burlington, MA., by letter on December 17, 2002. Firm initiated recall

is ongoing.

#### **REASON**

Defibrillator may fail to function due to false detection of safety fault condition.

#### **VOLUME OF PRODUCT IN COMMERCE**

5,597 units.

#### **DISTRIBUTION**

Nationwide.