U.S. Department of Health and Human Services
Food and Drug Administration

RECALLS AND FIELD CORRECTIONS: DEVICES -- CLASS I

M Series Advisory Defibrillator, M Series AED Defibrillator, ZOLL MEDICAL CORP.

Source: FDA Enforcement Report April 24, 2002
http://www.fda.gov/bbs/topics/enforce/2002/ENF00740.html

PRODUCT
a) Zoll M Series Advisory Defibrillator. Recall # Z-0893-2;
b) Zoll M Series AED Defibrillator (semi automatic defibrillator). Recall # Z-0894-2.
CODE
a) Serial Numbers: T98F00046-T01K27762 with System Software Version below 30.00
b) Serial Numbrs: T98F0092-T01J27533 with System Software Version below 30.0.
RECALLING FIRM/MANUFACTURER
Zoll Medical Corp., Burlington, MA, by letter on December 18, 2001. Firm initiated recall is ongoing.
REASON
Defibrillator may fail to detect ventricular fibrillation and fail to deliver shock.
VOLUME OF PRODUCT IN COMMERCE
13,667.
DISTRIBUTION
Nationwide and worldwide.