FDA

Enforcement Report

The FDA Enforcement Report is published weekly by the Food and Drug Administration, U.S. Public Health Service, Department of Health and Human Services. It contains information on actions taken in connection with agency regulatory activities.

April 12, 2000 **00-15**

RECALLS AND FIELD CORRECTIONS: DEVICES -- CLASS II

PRODUCT
LIFEPAK 500 Automated External Defibrillator (AED), designed to be used by first responders to cardiac emergencies. Recall #Z-442-0.
CODE
All serial numbers with more than 8 digits.
All serial numbers with 6 digits.
7 digit serial numbers less than 7925937 and serial number 8631084.
MANUFACTURER
Medtronic Physio-Control Corporation, Redmond, Washington.
RECALLED BY
Manufacturer, by Tech Memo #3 issued in June 1998, Tech Memo #3a on February 7, 2000, by Technical Service Update on March 23, 2000, and visit with letter dated March 2000. Firm-initiated field correction ongoing.
DISTRIBUTION
Nationwide and international.
QUANTITY
8,031 units were distributed.
REASON
Potential damage/failure of resistor R4 could result in unusable unit next use.