



MERCURY
M E D I C A L[®]

K954486

ENCLOSURE I

510(k) SUMMARY

- **Mercury Airway Pressure Manometer**
- **Airway Pressure Manometer (gauge)**
- **monitor, airway pressure (includes gauge)**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act 1990 and 21CFR 807.92.

The Mercury Airway Pressure Manometer is a disposable manometer intended to measure airway pressure up to 80 cm H₂O. It is designed to be attached by flexible tubing to the Mercury CPR bag or other devices providing expiratory pressure. Bench testing has determined that the Mercury Airway Pressure Manometer measures airway pressures up to 80 cm H₂O in a manner consistent with the Dwyer Magnahelic Gauge, a pre-amendment device.

Kathy L. Hann
Kathy L. Hann

9/22/95
Date