

K963120

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SECTION 2 - SUMMARY AND CERTIFICATION

2.1 510(k) Summary of Safety and Effectiveness

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

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Device: Trade Name: Responder 2500 Defibrillator and Cardiac Care System
Classification Name: DC-Defibrillator, low energy (including paddles)
Pacemaker, Cardiac, External Transcutaneous (Non-invasive)

Predicate Devices: Marquette Series 900
Marquette Series 1500 Responder

Device Description: Responder 2500 and Cardiac Care System is an emergency cardiac monitor/defibrillator with an external pacing option.

Intended Use: Responder 2500 is intended to be used in a hospital environment by emergency personnel in evaluating and treating life-threatening arrhythmias.

- ◆ Responder 2500 is intended to be used by trained operators
- ◆ Responder 2500 is designed for external and internal defibrillation (including cardioversion)
- ◆ Responder 2500 is capable of monitoring the heart rate with adjustable alarm limits.
- ◆ Responder 2500 is designed for external pacing with adjustable current and rate.

The intended use of Responder 2500 is identical to the intended use of the predicate devices.

Technology:

Responder 2500 employs the same technology as the predicate devices.

Performance:

Responder 2500 complies with the voluntary standards ANSI/AAMI DF2-1996, ANSI/AAMI ES1 1993, ANSI/AAMI EC13 1992, IEC 601-1, IEC 601-1-2, IEC 601-2-4, IEC 601-2-27, UL 2601-1.

The following quality assurance measures were applied to the development of Responder 2500.

Requirements specification reviews, code inspections, software and hardware testing, safety testing, environmental testing, field tests on the monitor function and animal studies on the defibrillation and pacing functions, and final validation.

The results of these measurements demonstrated that Responder 2500 is as safe, as effective, and performs as well as the predicate devices Marquette Series 900 and Marquette Series 1500 Responder.