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SECTION 2 - SUMMARY AND CERTIFICATION

MAR - 6 1997

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.

Submitter:

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Device:

Trade Name: CardioServ P
Classification Name: DC-Defibrillator, low energy (including paddles)
Pacemaker, Cardiac, External Transcutaneous (Non-invasive)

Predicate Devices:

HELLIGE CardioServ SCP 910
Marquette Series 1500 Responder

Device Description:

CardioServ is a portable defibrillator with ECG monitor, built-in recorder, and the capability of external pacing with adjustable current and frequency.

Intended Use:

CardioServ is intended to be used for the emergency resuscitation of cardiac arrest victims and clinical cardiac dysrhythmia.

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

The intended use of CardioServ is identical to the intended use of the predicate devices.

Technology: CardioServ employs the same technology as the predicate devices.

Performance: CardioServ complies with the voluntary standards ANSI/AAMI DF2-1989, ANSI/AAMI ES1 1993, IEC 601-1, IEC 601-1-2, IEC 601-2-4, EN 60601-2-31.

The following quality assurance measures were applied to the development of CardioServ:

Requirements specification reviews, code inspections, software and hardware testing, safety testing, environmental testing, final validation testing by an independent test group, field tests.

The results of these measurements demonstrated that CardioServ is as safe, as effective, and performs as well as the predicate devices CardioServ SCP 910 and Marquette Series 1500 Responder.