K955854

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510(k) Summary
(Summary of information contained in the 510(k) premarket notification)

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Device:

Physio-Control Corporation LIFEPAK® 500 Automated External Defibrillator

Classification:

Low-Energy DC - Defibrillators (including Paddles): Class II (21 CFR 870.5300) (Federal Register Vol. 45, No., 25; Tuesday, February 5, 1980)

Automatic External Defibrillators have been considered Class III devices by FDA.

Substantial Equivalence:

This defibrillator is substantially equivalent to the currently marketed Physio-Control LIFEPAK 300 automated external defibrillator (510(k) no. K943301) and the SurVIVAlink automated external defibrillator (510(k) no. K940445).

Description:

The LIFEPAK 500 Automated External Defibrillator (AED) is a portable battery powered device which applies a brief, high energy pulse of electricity to the heart via defibrillation electrodes on the chest. A software algorithm analyzes the patients electrocardiogram (ECG) and informs the operator whether it detects a shockable rhythm. The operator can then press the shock button to deliver energy after confirming that the patient is unconscious, pulseless and apneic.

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Intended Use:

The LIFEPAK 500 Automated External Defibrillator may be used in the hospital or pre-hospital setting by authorized personnel to terminate certain potentially fatal cardiac arrhythmias.

Technological characteristics of new and predicate devices:

The LIFEPAK 500 AED uses the same arrhythmia detection algorithm that is used in the LIFEPAK 300 AED.

Summary of Performance Information:

Performance test information provided in the 510(k) demonstrates substantial compliance with applicable sections of AAMI DF39-1993, "Automated External Defibrillators and Remote-Control Defibrillators," AAMI DF2-1989, "Cardiac Defibrillator Devices," and the FDA Reviewers Guidance for Premarket Notifications.

Tests include high and low temperature, high and low humidity, altitude, energy accuracy, pulse shape and duration, charge time, battery capacity, defibrillation recovery, rhythm detector function, EMC, dielectric withstand, leakage current, vibration and shock resistance, and rhythm detection.

Test information demonstrates that the safety and effectiveness of the LIFEPAK 500 are substantially equivalent to those of the predicate devices.