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510(k) SUMMARY; K955923

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Device Trade Name: Medi-Trace® 1110L Combination Defibrillation and ECG Electrode

Common Name: Self Adhesive Electrode for Monitoring and Defibrillation

Classification Name: Accessory to an automatic or semiautomatic defibrillator

Regulatory Reference: 74 MKJ

Predicate Device: Laerdal Heartstart® Defibrillation Electrode

Description: A pre-gelled conductive electrode consisting of a means of attaching the electrode to the cable, an insulating layer of vinyl, a layer of metal foil, a conductive adhesive hydrogel, a pressure sensitive adhesive ring and a release liner. Device is packaged in pairs in a heat sealed pouch, 10 pouches are packaged into one shelf-box/shipper.

Intended Use: Intended for use in defibrillation procedures. This device also allows for ECG monitoring. There are no population restrictions for the device except as noted in the directions for use.

Physical/Technical Comparison:

Medi-Trace® 1110L Electrode is replaceable with the Laerdal Heartstart® Defibrillation Electrode. Physical and technical characteristics, including materials used in construction, size, intended use and conductive gel type of these electrodes are comparable. Since formulation of conductive gel is considered proprietary, exact chemical comparisons could not be made.

Performance Summary:

The device was subjected to AAMI electrical tests as described in ANSI/AAMI DF39-1993 standard, part 3.3.19 and energy throughput testing. Test results indicated that this device meets or exceeds ANSI/AAMI specifications for electrical testing as established in DF39-1993, part 3.3.19 and labeling requirements as established in part 3.1.2 for self adhesive electrodes for monitoring and defibrillation.

Biocompatibility Testing:

The device was subjected to biocompatibility testing as recommended in the May 1, 1995 FDA memorandum entitled: *Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"*. The device was found to be non-irritating, non-cytotoxic and non-sensitizing.

Shelf Life:

Data obtained in accelerated shelf life studies was reviewed and found to substantiate our claimed shelf life.