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**510(k) SUMMARY; K955882**

**Date:** October 24, 1996

**Manufacturer:** Graphic Controls Corporation  
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**Device Trade Name:** Medi-Trace® 1210H Combination Defibrillation,  
Pacing and ECG Electrode

**Common Name:** Self Adhesive Electrode for Monitoring and  
Defibrillation, optional Pacing

**Classification Name:** Multi-Purpose Electrocardiograph Electrode

**Regulatory Reference:** 74 MLN

**Predicate Device:** Hewlett® Packard M1749A Multifunction Adult  
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, cardioversion and pacing. This device is intended for use on adults. Not for use on children or infants.

**Physical/Technical Comparison:**

Medi-Trace® 1210H Electrode is replaceable with the Hewlett® Packard M1749A Multifunction Adult 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 and the predicate were subjected to AAMI electrical tests as described in DF-39, 3.3.19 and energy throughput testing. Test results for both the device and the predicate met the specifications as established in DF-39 for self adhesive electrodes for monitoring, and defibrillation and pacing.

In addition, the device was subjected to simulated used testing consisted of multiple defibrillation shocks and maximum current pacing. Test results for the device met the specifications as established in DF-39 for self adhesive electrodes for monitoring, and defibrillation and pacing.

**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.