

MAY 12 1998

**510(k) SUMMARY**



Graphic Controls

**Date:** March 4, 1998

**Manufacturing Facility:** Graphic Controls Corporation  
189 Van Rensselaer Street  
P.O. Box 1271  
Buffalo, NY 14240  
Registration Number 1317188

**Telephone:** (716) 853-7500

**Contact Person:** Kathleen Selover  
Regulatory Affairs Specialist  
(716) 853-7500, extension 7630  
Fax: (716) 847-7531

**Device Trade Name:** Medi-Trace® 1310P Combination Defibrillation,  
Monitoring and Pacing Electrode

**Device Common Name:** Self Adhesive Defibrillation and Monitoring  
Electrode

**Classification Name:** Electrode, Electrocardiograph, Multifunction

**Regulatory Reference:** 74 MLN

**Predicate Device:** Physio Controls® Quik-Combo™  
Pacing/Defibrillation/ECG Electrode

**Description:** A pre-gelled conductive electrode consisting of a pre-attached leadwire, an insulating layer of a vinyl substrate, 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/Indications for Use:**

Intended for use in defibrillation procedures, cardioversion and pacing. This device is intended for use on adults and pediatric patients weighing over 10kg.

**Physical/Technical Comparison:**

Medi-Trace® 1310P Electrode is replaceable with the Physio-Controls® Quick Combo™ Pacing/Defibrillation/ECG Electrodes. Physical and technical characteristics, including materials used in construction, size, intended use and conductive gel type of these electrodes are comparable. Since the formulation of conductive gel is considered to be proprietary, exact chemical comparison could not be made.

**Performance Summary:**

The device and the predicate were subject to AAMI electrical tests as described in DF-39, 3.3.19 and energy through put testing. Test results for both the device and the predicate meet the specifications as established in DF-39 for self adhesive electrodes for monitoring, defibrillation and pacing.

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

**Biocompatibility Testing:**

The device was subjected to biocompatibility testing as recommended in ISO-10993, *Biological Evaluation of Medical Devices Part I: 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 were reviewed and found to substantiate our claimed shelf life.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Ms. Kathleen Selover  
Graphic Controls Corporation  
189 Van Rensselaer Street  
P.O. Box 1271  
Buffalo, NY 14240

Re: K980857  
Medi Trace® 1310P Combination Defibrillation,  
Monitoring and Pacing Electrode  
Regulatory Class: III (three)  
Product Code: 74 MLN  
Dated: March 4, 1998  
Received: March 5, 1998

Dear Ms. Selover:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions,

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular,  
Respiratory, and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number, if known: \_\_\_\_\_

Device Name: **Medi-Trace® 1310P Combination Defibrillation, Monitoring and Pacing Electrode**

Indications for Use:

Medi-Trace® 1310P Combination Defibrillation, Monitoring and Pacing Electrode is intended for use on adults and pediatric patients weighing over 10kg.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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\_\_\_\_\_ Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  \_\_\_\_\_

OR Over-the-Counter

Use \_\_\_\_\_ (Per 21CFR801.109)

*M. Pyglis*

\_\_\_\_\_  
(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number K980857