Graphic Controls Corporation

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Buffalo, New York 14240-1271 USA
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K972970

510(k) SUMMARY

AUG 27 1997

Graphic Controls

Date:	August 6, 1997
Manufacturing Facility:	Graphic Controls Corporation 189 Van Rensselaer Street PO Box 1271 Buffalo, NY 14240 Registration Number 1317188
Telephone:	(716) 853-7500
Contract Person:	Kathleen Selover Regulatory Affairs Specialist (71 6) 853-7500, ext 7630 Fax: (716) 847-7531
Device Trade Name:	Medi-Trace® 1510M Combination Defibrillation, Monitoring and Pacing Electrode
Device Common Name:	Self Adhesive Electrode for Monitoring and Defibrillation, optional Pacing
Classification Name:	Multi-function Electrocardiograph Electrode
Regulatory Reference:	74 MLN
Predicate Device	Marquette Electronics Defibrillation/Pacing Pads

Description:

A pre-gelled conductive elecrode 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/Indications for 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® 1510M Electrode is replaceable with Marquette Electronics Defibrillation/Pacing Pads. 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 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 mointoring, 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 moinitoring, 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

AUG 27 1997

Susan A. Krasny, Ph.D.
Graphic Controls Corporation
189 Van Rensselaer Street
P.O. Box 1271
Buffalo, New York 14240-1271

Re: K972970
Medi-Trace® 1510M Combination Defibrillation, Monitoring and Pacing Electrodes
Regulatory Class: III (three)
Product Code: 74 MLN
Dated: August 6, 1997
Received: August 11, 1997

Dear Dr. Krasny:

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, or other Federal laws or regulations.

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,

for 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: K972970

Device Name: **MediTrace® 1510M Combination Defibrillation, Monitoring and Pacing Electrode**

Indications for Use:

Medi-Trace 1510M Combination Defibrillation, Monitoring and Pacing Electrode is intended for use on adults. Not for use on children or infants.

(PLEASE DP MPT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K972970

Presecription Use ✓ OR Over-the-Counter Use _____(Per 21CFR 801.109)