Graphic Controls Corporation
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Buffalo, New York 14240-1274 USA
716 853-7500

Customer Relations: 800 669-1009
Fax: 800-347-2421

K981964

NOV 13 1998

# 510(k) SUMMARY

Graphic Controls

| | |
|---|---|
| **Date:** | June 2, 1998 |
| **Manufacturing Facility:** | Graphic Controls Corporation<br>Acadia Properties<br>Chase Street<br>Methuen, MA 01844<br>Registration Number: 12118874 |
| **Telephone:** | (716) 853-7500 |
| **Contract Person:** | Kathleen Selover<br>Regulatory Affairs Specialist<br>(71 6) 853-7500, ext 7630<br>Fax: (716) 847-7531 |
| **Device Trade Name:** | Medi-Trace® 4103 Neonatal ECG Electrode with Preattached Lead Wire |
| **Device Common Name:** | Neonatal ECG Monitoring Electrode |
| **Classification Name:** | Electrocardiograph Electrode |
| **Regulatory Reference:** | 74 DRX |
| **Predicate Device** | Graphic Controls Medi-Trace® 4103 Neonatal Electrode with Preattached Lead Wire |

**Description:**

A neonatal ECG monitoring electrode consisting of a conductive adhesive gel, a silver/silver chloride plated eyelet, a foam substrate and vinyl label and a 24 inch lead wire terminating in a 0.059" DIN standard safety socket.

**Intended Use:**

Intended for use whenever cardiac monitoring of neonatal or pediatric patients is deemed or desirable by trained medical or emergency personnel. This electrode is for use on neonatal and pediatric patients.

**Physical/Technical Comparison**

The modified Medi-Trace® 4103 electrode is equivalent to the Medi-Trace® 4103 electrode currently marketed by Graphic Controls Corporation. Physical and technical characteristics, including materials used in construction, size, intended use, indications for use for the modified device and the predicate are comparable.

**Performance Summary:**

The device and the predicate were subjected to AAMI electrical tests as described in ANSI/AAMI voluntary standard, DF-12, 1991, Disposable ECG Electrodes. Test results for both the device and the predicate met the specifications as established in DF-12-1991/

In addition to the requirements of DF-12-1991, the modified device was found comparable to the predicate for ECG trace quality.

**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 20850

NOV 13 1998

Susan Krasny, Ph.D.
Graphic Controls Corporation
P.O. Box 1274
189 Van Rensselaer Street
Buffalo, NY 14240

Re: K981964
Meditrace® 4103 Neonatal Electrode
Regulatory Class: II (two)
Product Code: 74 DRX
Dated: August 25, 1998
Received: August 26, 1998

Dear Dr. Krasny:

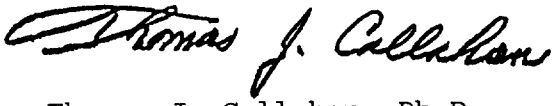
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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" (21CFR 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/dsma/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: K981964

Device Name: Medi-Trace® 4103 Neonatal Electrode with Preattached lead wire

Indications for Use:

Whenever cardiac monitoring is deemed necessary or desirable by trained medical or emergency personnel. This electrode is for use on neonatal and pediatric patients.

(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 K981964

Prescription Use X OR Over-the-Counter Use _____(Per 21CFR 801.109)