

Graphic Controls Corporation

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Graphic Controls



Date: October 25, 1996

Manufacturer: Graphic Controls Corporation
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PO Box 1271
Buffalo, NY 14240
Registration Number 1317188

Manufacturing Location: Graphic Controls, Canada, Ltd.
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Device Trade Name: Medi-Trace® 200 and Medi-Trace® 200-30 ECG Electrodes

Common Name: Disposable ECG Monitoring Electrode

Classification Name: Electrocardiograph Electrode

Regulatory Reference: 74 DRX

Predicate Device: Medi-Trace® 500 Electrodes

Description: A conductive wet gel electrode consisting of a conductive adhesive gel, a silver/silver chloride plated ABS eyelet, nickel plated brass stud, an adhesive foam substrate, vinyl label and polystyrene release liner. Electrodes are packaged either as 100 per pouch (Medi-Trace® 200) or 30 per pouch (Medi-Trace® 200-30); pouches are heat sealed.

Unit of sale for each packaging is a case of either 600 or 1000 electrodes.

Intended Use: Intended for use in general electrocardiograph procedures where ECG monitoring is deemed necessary and is ordered by a physician.

Physical/Technical Comparison:

Medi-Trace® 200 is equivalent to the predicate device. Physical and technical characteristics, including materials used in construction, size, intended use and conductive gel type of device and the predicate are comparable.

Performance Summary:

The device and the predicate were subjected to AAMI electrical performance tests as described in EC12-1991. Test results indicate that this device meet or exceeds the the performance specifications as established in EC12-1991 for Disposable ECG Electrodes. In addition, the device was found to meet EC12-1991 AAMI standard for labeling, shelf life, packaging and safety and Graphic Controls' internal specifications for trace performance.

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 real time shelf life studies was reviewed and found to substantiate our claimed shelf life.