

**510(K) Summary**

**APR -9 1997**

**Name and address of device Manufacturer submitting 510(k) Notification:**

3M Health Care  
3M Center  
St. Paul, MN 55144-1000

**Regulatory Correspondent of Device Manufacturer:**

Linda Johnsen  
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612 737-4376

**Date Summary was prepared:** March 3, 1997

**Name of Device:**

3M Red Dot™ 2560 Monitoring Electrode with Foam Tape and Sticky Gel

3M Red Dot™ 2570 Radiolucent Monitoring Electrode with Foam Tape, Sticky Gel and Abrader

**Classification:** Electrocardiograph electrodes, class II, 21 CFR 870.2360

**Description:** The 3M Red Dot™ 2560 & 2570 ECG Monitoring Electrodes are a self-adhesive, non-sterile, single use disposable electrode which includes a silver/silver chloride sensing element and conductive sticky gel. These electrodes include a pressure sensitive adhesive foam tape which hold the conductive elements of the electrode in place on the patient's skin for short or long term ECG procedures.

**Intended Use:** The 3M Red Dot™ 2560 & 2570 Monitoring Electrodes are intended for use in ECG Monitoring. The 2560 and 2570 electrodes can be used in all ECG applications where standard ECG monitoring electrodes are used. These electrodes can be used for short term and long term (up to 5 Days) monitoring.

**Safety and Efficacy:**

**Biocompatibility Testing:**

The biological safety of the Red Dot™ 2560 and 2570 Monitoring Electrodes has been assured through the selection of materials which demonstrate appropriate levels of biocompatibility. Tests were selected on the basis of Part-1 of ISO 10993-1, "Biological Evaluation of Medical Devices".

**Performance Testing:**

The electrical performance of the 3M Red Dot™ 2560 and 2570 Monitoring Electrodes meets the voluntary standard requirements under ANSI/AAMI EC12/1991, for Disposable ECG Electrodes.