K954900

JUL 15 1996

510(k) Summary
3M Red Dot™ ECG Lead Wires

1. Name and address of Device Manufacturer submitting 510(k) Notification:

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

2. Regulatory Correspondent of Device Manufacturer:

Linda Johnsen
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3M Health Care
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St. Paul, MN 55144-1000
612 737-4376

3. Date Summary was prepared: October 23, 1995

4. Name of Devices:

   (a) 3M Red Dot™ ECG Lead Wires

   (b) Common, usual name: Lead Wires

   (c) Proprietary names of the devices: 3M Red Dot™ ECG Lead Wires

   (d) Regulatory Class: ECG Lead Wires have been classified as a Class II device. See 21 C.F.R. 870.2360. This device was reviewed by the Cardiovascular Device Panel.

5. Predicate Devices to which 3M is claiming Substantial Equivalence:

Tronomed	510(k) K771645	**P/N D-3A1505-8-C**
Vital Connections	510(k) K880320	**P/N RTR 5925**

6. Description of the Devices:

Components of the Device:

This device is a patient lead wire. These patient lead wires are manufactured from a variety of electronic conductors, electronic insulating materials, patient end termination and patient lead wire connectors. This variety of materials and assembly configurations is needed to allow for designs that would be disposable, reusable, x-ray translucent or non x-ray translucent. These materials are all typically and commonly used by other companies participating in the market. The following matrix demonstrates for the purpose of substantial equivalence the similarity of product features:

PRODUCT FEATURE	3M DISPOSABLE	3M STANDARD	3M HIGH FLEX	D-3A1505-8-C Tronomed	RTR 5925 Vital Connections
WIRE	YES	YES	YES	YES	YES
X-RAY TRANSLUCENT	YES	YES	YES	NO	YES
SHIELDED	YES	YES	YES	YES	YES
PATIENT LEADWIRE CONNECTOR	YES	YES	YES	YES	YES
PATIENT END TERMINATION	YES	YES	YES	YES	YES

Principle of Operation:

The ECG lead wire is intended only for the purpose of connecting an ECG monitoring electrode to either an ECG monitor trunk cable or directly into a monitor or transmitter and conducting the patients ECG signal.

7. Effectiveness:

3M will meet the minimum requirements established by proposed AAMI specifications as to Flex Life, Tensile Strength, and Electrical Continuity.