510(K) Summary

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

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

Regulatory Correspondent of Device Manufacturer:

Linda Johnsen
Regulatory Affairs Specialist
3M health Care
Building 275-3E-08
612 737-4376

Date Summary was prepared: November 21, 1997

Name of Device: 3M Red Dot™ Resting EKG Electrode, Catalog Number 2360

Classification: Electrocardiograph electrodes, class II, 21 CFR 870.2360

Description:
3M Red Dot™ Resting EKG Electrode, Catalog Number 2360 has a conductive adhesive which is laminated to a conductive Ag/AgCl backing. The conductive backing has a tab end for connection to the electrocardiograph leadwire.

Indications for Use:
The 3M Red Dot™ Resting EKG Electrode can be used on a patient undergoing an EKG diagnostic procedure while resting. These electrodes are applied to the patient's skin for short term use. These electrodes are disposable and are for single use. They are not indicated for use in long term monitoring.

Predicate Device:
The predicate device used for the purpose of substantial equivalence and used for comparison was 3M Red Dot™ Resting EKG Electrode, Catalog Number 2330 which was filed and cleared under 510(k) Number k932454. The significant difference between the 2330 and 2360 is that the 2360 introduces a new conductive adhesive which increases the adhesion of the electrode. The electrode backing and liner of the 2360 are also different but the changes are minor when compared to the 2330.

Safety and Efficacy:

Biocompatibility Testing:
The biological safety of the Red Dot™ 2360 Resting EKG Electrode 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™ 2360 Resting EKG Electrode has been tested and meets the voluntary standard requirements under ANSI/AAMI EC12/1991, for Disposable ECG Electrodes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 26 1998

Ms. Linda Johnsen
Regulatory Affairs Specialist
3M Health Care
3M Center, Building 275-3E-08
St. Paul, MN 55114-1000

Re: K974445
3M Red Dot™ Resting EKG Electrode Model 2360
Regulatory Class: II (two)
Product Code: DRX
Dated: April 22, 1998
Received: April 27, 1998

Dear Ms. Johnsen:

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,

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): _____

Device Name: 3M Red Dot™ 2360 EKG Resting Electrode

Indications For Use:

The 3M Red Dot™ Resting EKG Electrode can be used on a patient undergoing an EKG diagnostic procedure while resting. These electrodes are applied to the patient's skin for short term use. These electrodes are disposable and are for single use. They are not indicated for use in long term monitoring.

These electrodes will include the precaution statement: U.S.A. Federal Law restricts this device to sale by or on the order of a physician.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K974445