

510(k) Summary

K971444

Name and address of device Manufacturer submitting 510(k) Notification: June 11, 1997

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

Regulatory Correspondent of Device Manufacturer:

Linda Johnsen
Senior Regulatory Affairs Associate
612 737-4376

Date Summary was prepared: April 17, 1997

Name of Device: 3M™ Red Dot™ 2234 Radiolucent Monitoring Electrode with Clear Tape and
3M™ Red Dot™ 2266 Radiolucent Monitoring Electrode with Breathable Comfort Back

Classification: Electrocardiograph electrodes, class II, 21 CFR 870.2360

Description: The 3M™ Red Dot™ 2234 & 2266 Radiolucent Monitoring Electrodes are a self-adhesive, non-sterile, single use, disposable electrode which includes a silver/silver chloride sensing element and conductive gel. These electrodes include a self-adhesive tape backing which holds the conductive elements of the electrode in place on the patient's skin for short or long term (up to 3 days) for ECG monitoring. The 3M™ Red Dot™ 2234 & Radiolucent Monitoring Electrode with Clear Tape is composed of the same materials as the predicate device 3M™ Red Dot™ 2234 Radiolucent Monitoring Electrode (K939312) with the exception of the snap which has been modified to include a higher percentage of carbon. The 3M™ Red Dot™ 2266 Radiolucent Monitoring Electrode with Breathable Comfort Backing is composed of the same materials as the predicate device 3M™ Red Dot™ 2234 Radiolucent Monitoring Electrode (K939312) with the exception of the sensing snap which has been modified to include a higher percentage of carbon and the tape backing and adhesive.

Indications for use: The 3M™ Red Dot™ 2234 & 2266 Radiolucent Monitoring Electrodes are intended for use in ECG Monitoring Procedures. The 2234 & 2266 Radiolucent Monitoring 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 3 days) monitoring.

Safety and Efficacy: (Devices are acceptable for their intended use based on testing results)

Biocompatibility Testing:

The biological safety of the 3M™ Red Dot™ 2234 and 2266 Radiolucent 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™ 2234 and 2266 Radiolucent Monitoring Electrodes meets the voluntary standard requirements under ANSI/AAMI EC12/1991, for Disposable ECG Electrodes.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 1997

Ms. Linda Johnsen
3M Health Care
3M Center, Building 275-3E-08
St. Paul, Minnesota 55144-1000

Re: K971444
* 3M™ Red Dot™ 2234 & 2266 Radiolucent Monitoring Electrodes
(Modified)
Regulatory Class: II (two)
Product Code: 74 DRX
Dated: April 18, 1997
Received: April 21, 1997

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.

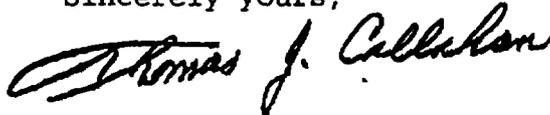
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

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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): K971444

Device Name: 3M™ Red Dot™ 2234 Radiolucent Monitoring Electrode with Clear Tape and 3M™ Red Dot™ 2266 Radiolucent Monitoring Electrode with Breathable Comfort Back

Indications For Use:

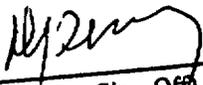
* The 3M™ Red Dot™ 2234 & 2266 Radiolucent Monitoring Electrodes are intended for use in ECG Monitoring. The 2234 and 2266 electrodes can be used in all ECG applications where standard ECG monitoring electrodes are used. These electrodes can be used for short term and long term (up to 3 days) monitoring.

These devices are a single use, non-sterile, and disposable ECG electrode. These devices adhere to the patient's skin.

These electrodes will include the precaution statement: USA 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)



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K971444

Prescription Use
(Per 21 CFR 801.109)

OR

Over-the Counter Use

(Optional Format 1-2-96)