K973419

**_Nellcor Puritan Bennett_ DMR² Plus™ Disposable Manual Resuscitator with integrated CO2 detection**
**510(k) Summary**
**December 18, 1997**


MAR 25 1998

## 1. Company Information

| | |
|---|---|
| Establishment: | Nellcor Puritan Bennett Inc.<br>4280 Hacienda Drive<br>Pleasanton, CA 94588<br>(510) 463-4177 |
| Official Correspondent: | Sheryll A. Mathews<br>Regulatory Affairs Assistant |

## 2. Device Name

| | |
|---|---|
| Proprietary: | DMR² Plus™ Disposable Manual Resuscitator with integrated CO2 detection |
| Common/Usual: | Disposable Manual Resuscitator with integrated CO2 detection |
| Classification: | 73BTM |

## 3. Equivalent Device

1. *CAPNO-FLO*™ End-Tidal CO2 Detector/Monitor - Kirk Specialty Systems - K933626
2. *Nellcor Puritan Bennett* DMR/CO2 Combo Kit - K960468

## 4. Device Description

The DMR² Plus™ Disposable Manual Resuscitator with integrated CO2 detection is a portable, nonsterile, single-patient use device intended for use on patients requiring manual ventilatory support.

The DMR² Plus™ is available in three sizes: adult, child and infant. It may be used by qualified healthcare professionals in any environment where pulmonary support resuscitation is indicated; such as, hospital, transport, mobile and home.

The DMR² Plus™ consists of a compressible resuscitator bag that is available in either processed natural rubber or PVC. The swivel, patient connection and CO2 detector cartridge are connected to the non-rebreathing Valve (NRV) housing - all housings are K-resin. The oxygen accumulator assembly enables the use of three different styles of oxygen accumulators: large bore, small bore or flat bag.

During artificial ventilation, the resuscitator can be operated from ambient air or provide oxygen-enriched air using the oxygen accumulator and connecting the supply tubing to a metered oxygen source. The integrated CO2 detector can be used to assist the verification of tube placement during endotracheal or nasotracheal intubation. The integrated CO2 detector detects approximate ranges of CO2 by color comparison.

## 5. Intended Use

The DMR² Plus™ Disposable Manual Resuscitator with integrated CO2 detection is a portable, nonsterile, single-patient use device intended for use on patients requiring manual ventilatory support. During artificial ventilation, the resuscitator can be operated from ambient air or provide oxygen-enriched air using the oxygen accumulator and connecting the supply tubing to a metered oxygen source. The integrated CO2 detector can be used to assist the verification of tube placement during endotracheal or nasotracheal intubation. The integrated CO2 detector detects approximate ranges of CO2 by color comparison.

The DMR² Plus™ is available in three sizes and are intended for use on the following patient populations:

- **Adult** is indicated for use on adults >40 kg.
- **Child** is indicated for use on children 10 - 40 kg.
- **Infant** is indicated for use on infants 5 - 10 kg

The DMR² Plus™ is intended for use by qualified healthcare professionals in any environment where pulmonary support resuscitation is indicated such as hospital, transport, mobile and home.

## 6. Technological Characteristics

The method of operation and the CO2 detector technology of the DMR² Plus™ are equivalent to the CAPNO-FLO and the *Nellcor Puritan Bennett* DMR/CO2 Combo Kit. A comparison of the devices' design features, methods of operation and labeling support technical equivalency.

The safety and effectiveness of the DMR² Plus™ has been demonstrated by design and testing. Testing was conducted in accordance with the requirements of ISO 8382: *Resuscitators Intended for Use With Humans*; ISO 5356-1: *Anaesthetic and respiratory equipment - Conical connectors*; and ASTM F 920-93: *Standard Specification for Minimum Performance and Safety Requirements for Resuscitators Intended for Use With Humans.*

In addition, environmental testing was conducted as recommended by applicable sections of the *Draft Reviewer's Guidance for Premarket Notification Submissions*, November 1993.

Test results demonstrate and/or labeling indicates how all applicable requirements have been addressed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 25 1998

Ms. Sherry Mathews
Nellcor Puritan Bennett Inc.
4280 Hacienda Drive
Pleasanton, CA 94588-2719

Re: K973419
DMR$^2$ Plus Disposable Manual Resuscitator
Regulatory Class: II (two)
Product Code: 73 BTM
Dated: January 7, 1998
Received: January 9, 1998

Dear Ms. Mathews:

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):** Unknown K973419

**Device Name:** DMR² Plus™ Disposable Manual Resuscitator with integrated CO2 detection

**Indications For Use:**

The DMR² Plus™ Disposable Manual Resuscitator with integrated CO2 detection is a portable, nonsterile, single-patient use device intended for use on patients requiring manual ventilatory support. During artificial ventilation, the resuscitator can be operated from ambient air or provide oxygen-enriched air using the oxygen accumulator and connecting the supply tubing to a metered oxygen source. The integrated CO2 detector can be used to assist the verification of tube placement during endotracheal or nasotracheal intubation. The integrated CO2 detector detects approximate ranges of CO2 by color comparison.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

3/29/98 C. Chang for Supervisor, Branch Chief

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

510(k) Number

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)