

Non-Confidential Summary of Safety and Effectiveness

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May 28, 1999

Engineered Medical Systems, Inc.
2055 Executive Dr.
Indianapolis, IN 46241

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Official Contact: Bonnie Holly - Quality Manager

Proprietary or Trade Name: EMS Disposable Manual Resuscitator with CO₂ Detection

Common/Usual Name: Disposable Manual Resuscitator with CO₂ Detection

Classification Name: Emergency Manual Ventilator Resuscitator

Device: EMS Disposable Manual Resuscitator with CO₂ Detection

Predicate Devices: EMS Disposable Manual Resuscitator with CO₂ Detection - K912203B and K924610A
 Nellcor Puritan Bennett - DMR2 Plus Manual Resuscitator with CO₂ Detection - K973419
 Nellcor Puritan Bennett - EasyCap CO₂ Detector - K894053 and K944400

Device Description

The EMS Disposable Manual Resuscitator is a bag-valve-mask device with the capability of delivering supplemental oxygen. It incorporates a feature CO₂ detection.

Intended Use

Indicated Use -- Intended for use where pulmonary support resuscitation is indicated and exhaled CO₂ detection is desirable.

Environment of Use -- Hospital, Transport, Mobile and Home settings

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Comparison to Predicate Devices:

Attribute	EMS DMR with CO ₂ (Modification)	EMS DMR K912203B K924610A	NPB DMR Plus with CO ₂ K973419
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Use

Intended to provide manual ventilatory support	Yes	Yes	Yes
Intended to assist in verification of tube placement by expired CO ₂ detection	Yes	--	Yes
Used in hospitals, home, transport mobile settings	Yes	Yes	Yes
Single Patient Use	Yes	Yes	Yes

Design

CO ₂ detector placed on expiratory port of manual resuscitator	Yes	--	Yes
CO ₂ detection by color comparison	Yes	--	Yes
CO ₂ detector good for up to 2 hours	Yes	--	Yes
Can be replaced if needed	Yes	--	Yes

Materials

Materials in CO ₂ detection media the exactly the same as predicate	Yes	--	Yes
All other materials exactly the same as predicate	Yes	Yes	--

Packaging

Provided clean, non-sterile	Yes	Yes	Yes
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Performance Standards / Specifications

None applicable under Section 514	Yes	Yes	Yes
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Differences Between Other Legally Marketed Predicate Devices

There are no differences between the proposed modification, that of adding CO₂ detection capabilities to the exhalation port of the manual resuscitator, and the predicates.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 6 1999

Ms. Bonnie Holly
Engineered Medical Systems
2055 Executive Drive
Indianapolis, IN 46241

Re: K991955
Disposable Manual Resuscitator with CO₂ Detection
Regulatory Class: II (two)
Product Code: 73 BTM
Dated: May 28, 1999
Received: June 1, 1999

Dear Ms. Holly:

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 legally marketed predicate 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.

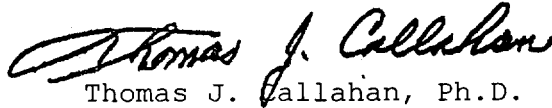
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Ms. Bonnie Holly

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/dsma/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

INDICATIONS FOR USE

Pursuant to the Notice of February 6, 1996 regarding listing of Indications for Use on a separate sheet, the following is per that request.

510(k) Number: _____ (To be assigned)

Device Name: EMS Disposable Resuscitator with CO₂ Detector

Intended Use : Disposable manual resuscitator with CO₂ detection for use with patients requiring manual ventilatory support. The CO₂ detector is located on the expiratory port. It may be supplied separately and attached to any resuscitator expiratory port. The CO₂ detector assists in verification of the endotracheal tube placing during endotracheal or nasotracheal intubation. The CO₂ detector detects approximate ranges of CO₂ by color comparison. It is intended for use by qualified healthcare professionals in any environment where pulmonary support resuscitation is indicated such as in the hospital, transport, mobile or home settings.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Arthur A. Liebowitz

Division Sign-Off
Division of Cardiovascular, Respiratory,
Neurological Devices
Device Number K991955

Prescription Use
(Per CFR 801.109)

or

Over-the-counter use