K991953

JUL - 1 1999

EMS Engineered Medical Systems ISO 9001 Certified

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Non-Confidential Summary of Safety and Effectiveness

May 28, 1999

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

Tel - (317) 246-5500

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Official Contact: Bonnie Holly - Quality Manager

Proprietary or Trade Name: EMS Disposable Manual Resuscitator with CO_2 Detection

Common/Usual Name: Disposable Manual Resuscitator with CO_2 Detection

Classification Name: Emergency Manual Ventilator Resuscitator

Device: EMS Disposable Manual Resuscitator with CO_2 Detection

Predicate Devices: EMS Disposable Manual Resuscitator with CO_2 Detection - K912203B and K924610A

Nellcor Puritan Bennett - DMR2 Plus Manual Resuscitator with CO_2 Detection - K973419

Nellcor Puritan Bennett - EasyCap CO_2 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 CO_2 detection.

Intended Use

Indicated Use -- Intended for use where pulmonary support resuscitation is indicated and exhaled CO_2 detection is desirable.

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

Comparison to Predicate Devices:

Attribute	EMS DMR with CO_2 (Modification)	EMS DMR K912203B K924610A	NPB DMR Plus with CO_2 K973419
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
Performance Standards / Specifications			
None applicable under Section 514	Yes	Yes	Yes

Differences Between Other Legally Marketed Predicate Devices

There are no differences between the proposed modification, that of adding CO_2 detection capabilities to the exhalation port of the manual resuscitator, and the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K991953
Disposable Manual Resuscitator with CO_2 Detection
Regulatory Class: II (two)
Product Code: 73 BTM
Dated: May 28, 1999
Received: June 1, 1999

Dear Ms. Holly:

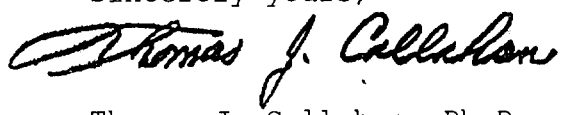
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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.

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 CO_2 Detector

Intended Use : Disposable manual resuscitator with CO_2 detection for use with patients requiring manual ventilatory support. The CO_2 detector is located on the expiratory port. It may be supplied separately and attached to any resuscitator expiratory port. The CO_2 detector assists in verification of the endotracheal tube placing during endotracheal or nasotracheal intubation. The CO_2 detector detects approximate ranges of CO_2 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)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K991953

Prescription Use ✓ **or** **Over-the-counter use** __
(Per CFR 801.109)