4-7-99

K983919

EMS Engineered Medical Systems

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Non-Confidential Summary of Safety and Effectiveness

December 18, 1998

Engineered Medical Systems, Inc.
8529 Zionsville Rd.
Indianapolis, IN 46268

Tel - (317) 872-5500

Fax - (317) 872-4052

Official Contact: Jeff Quinn - President

Proprietary or Trade Name: EMS Mouth to Mask resuscitators

Common/Usual Name: Mouth to Mask resuscitators

Classification Name: Non-rebreathing valve

Device: EMS Mouth to Mask resuscitators

Predicate Devices: EMS Mouth to Mask resuscitators - K881086
Formosa cj Health Partners - CPR Super - K953230
Intertech - MTM - K871407

The EMS Mouth to Mask resuscitators are a combination of components which include a face mask, one way valve, filter and mouthpiece offered with different sizes of face mask, packaging, clam shell and poly bag, and with or without flex tube extension. They are available in several styles -

Flex Tube which is an assembly of a flex tube, mouthpiece, one way valve and face mask (can be different sizes). This product is preassembled and packaged in a poly bag.

Collapsible style - This product includes a one way valve and a face mask which can be collapsed to fit into a "clam shell" style package. Besides the face mask being designed to collapse, the one way valve and mouthpiece can be removed so that all the components fit into the clam shell package.

Each style - Flex Tube and Collapsible - can incorporate a supplemental oxygen delivery port. This port is located on the one way housing. This port is a standard tapered fitting which connects to standard oxygen tubing.

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[redacted]

Indicated Use -- Indicated to provide assisted ventilation to someone requiring assisted ventilation, breathing or resuscitation, by use of a mouth to mask method. Patient population is child / infant and adult. Those with oxygen port are prescription devices and those without the oxygen port are OTC.

Environment of Use -- Hospital, Emergency Services, Home

[redacted]

[redacted] EMS [redacted]

[redacted]		
Indicated for use in resuscitation	Yes	Yes
To be placed in contact with the patient's face	Yes	Yes
Indicated for single use	Yes	Yes
Indicated population - adult and child / infant	Yes	Yes
Environment Home, EMS, Hospital	Yes	Yes
Unit with oxygen port prescription device	Yes	Yes
Unit without oxygen port is OTC	Yes	Yes

[redacted]		
Utilizes a face mask for patient seal	Yes	Yes
Face mask cushion pre-inflated	Yes	Yes
Offered in 2 face mask sizes	Yes	Yes
Made in clear materials	Yes	Yes
Utilizes a one way valve to direct air flow from user to patient	Yes	Yes
Exhaled patient breath diverted to atmosphere away from giver	Yes	Yes
Has an integral particulate / barrier filter	Yes	Yes
Has a flex tube and mouth piece	Yes	Yes
Packaged in a "clam shell" or poly bag	Yes	Yes
Can incorporate an oxygen delivery port	Yes	Yes

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Materials of filter media - 3 M Filtrete	Yes	Yes
Mask cushion - PVC	Yes	Yes
Duckbill valve / one way - SR synthetic rubber	Yes	Yes
Housing materials - Polycarbonate, K-resin	Yes	Yes
Extension tube - Polyethylene	Yes	Yes
Elastic band - polypropylene (PP), latex	Yes	Yes
Case - polyethylene (PE)	Yes	Yes
Filtration efficiency claims	None	None
Meets appropriate sections of ASTM 920-93	Yes	Yes
None required under Section 514	Yes	Yes

There are no significant differences between the intended devices and the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 7 1999

Mr. Jeff Quinn
President
Engineered Medical Systems
8529 Zionsville Road
Indianapolis, IN 46268

Re: K983919
Trade Name: EMS Mouth to Mask Resuscitators
Regulatory Class: II
Product Code: CBP
Dated: February 10, 1999
Received: February 11, 1999

Dear Mr. Quinn:

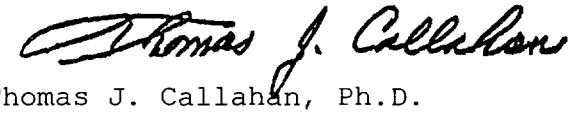
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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) 594-4586. 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" (21CFR 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

SECTION 2

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 Mouth to Mask Resuscitators

Intended Use: Indicated to provide assisted ventilation to someone requiring assisted ventilation, breathing or resuscitation, by use of a mouth to mask method. Patient population is child / infant and adult.

Those with oxygen port are prescription devices and those without the oxygen port are OTC.

Environment of use: Hospital, Emergency Medical Services

Concurrence of CDRH, Office of Device Evaluation (ODE)

Arthur A. Cardwell

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K983919

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