JAN 22 1999

K983920

EMS Engineered Medical Systems

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Non-Confidential Summary of Safety and Effectiveness

November 2, 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 Adjustable PEEP Valve

Common/Usual Name: PEEP valve

Classification Name: Breathing attachment - positive end expiratory pressure

Device: EMS PEEP Valve

Predicate Devices: EMS PEEP valve - K932799

Ambu - PEEP - K923976

Intertech - PEEP - K# unknown

Device Description:

The EMS PEEP valve is a adjustable valve which is placed in circuit and provides for positive end expiratory pressure for the patient. It is a spring actuated valve which adjusts from 0 to 20 cm H_2O.

Intended Use:

Indicated Use -- Indicated as an accessory to provide positive end expiratory pressure breathing capabilities to manual resuscitators, therapeutic CPAP systems and ventilator circuits.

Environment of Use -- Hospital, Emergency Services

Comparison to Predicate Devices:

Attribute	EMS Adjustable	Ambu K9323976	Intertech K# unknown
Use			
Indicated for providing positive end expiratory pressure	Yes	Yes	Yes
Used on manual resuscitators	Yes	Yes	Yes

Comparison to Predicate Devices:

Attribute	EMS Adjustable	Ambu K9323976	Intertech K# unknown
Use			
Used with therapeutic CPAP systems	Yes	Yes	yes
Placed in the breathing circuit	Yes	Yes	Yes
Intended to be single patient	Yes	Yes	Yes
Environment Home, EMS	Yes	Yes	Yes
Design			
Adjustable pressure range 0-20 cm H_2O	Yes	Yes	Yes
Fitting 19, 22, 30 mm	Yes	Yes	Yes
Spring actuated tension	Yes	Yes	Yes
Materials			
Materials of housing Polycarbonate, K-resin, propionate	Yes	Yes - K-resin, Polycarbonate	Yes
Spring - stainless steel	Yes	Yes	Yes
Performance Standards / Specifications			
None required under Section 514	Yes	Yes	Yes

Differences between Other Legally Marketed Predicate Devices

There are no significant differences between the intended device and the predicate - EMS PEEP valves - K932799, Ambu - K923976 and Intertech - K unknown.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 22 1999

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

Re: K983920
PEEP valves
Regulatory Class: II (two)
Product Code: BYE
Dated: November 2, 1998
Received: November 4, 1998

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) 594-4648. 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" (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

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: K983920 (to be assigned)

Device Name: EMS PEEP Valves

Intended Use: Indicated as an accessory to provide positive end expiratory pressure breathing capabilities to manual resuscitator, therapeutic CPAP systems, ventilator circuits. Available in 19mm, 22mm and 30 mm fittings. Pressure range from 0 to 20 cm H_2O

Environment of use: Hospital, Emergency Medical Services

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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

510(k) Number _____