K972605

JAN 28 1998

EMS Engineered Medical Systems

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Non-Confidential Summary of Safety and Effectiveness

July 8, 1997

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

Tel - (317) 872-5500

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Official Contact:	Bonnie Holly - Quality Manager
Proprietary or Trade Name:	EMS Nasal CPAP Mask and Accessories
Common/Usual Name:	Face Mask
Classification Name:	Anesthetic Gas mask
Device:	EMS Nasal CPAP mask
Predicate Devices:	Respironics Silicone Contour Nasal CPAP mask - K883825

Device Description:

The EMS Nasal CPAP mask is a mask covering the nose of a patient. It provides a seal such that positive pressure from a positive pressure source is directed to the patient's nose. It connects to a patient circuit which contains an exhalation device, tubing and perhaps a humidifier and/or bacteria filter. It is held in place with an adjustable headgear system. It made to be cleaned by soap and water.

There are optional accessories which may assist in providing more patient comfort - Foam Spacers help to reduce excessive headgear tension and relieve pressure on the bridge of the nose and Cushion Support Ring which supports the wall of the cushion.

Intended Use:

Indicated Use --	Same indication for the equipment to which it is the mask is attached
Environment of Use --	Hospital and Home
Equipment --	CPAP and Bi-level positive pressure systems, e.g. Respironics REM Star CPAP and BiPAP Systems, with a separate exhalation device and 22 mm flexible tubing.

Comparison to Predicate Devices:

Attribute	EMS Nasal CPAP	Respironics Contour Nasal Mask K883825
Use		
Same indications as equipment to which it is attached such as CPAP and Bi-level devices	Yes	Yes
Used on adults with OSA	Yes	Yes
Intended to be single patient - multi-use	Yes	Yes
Environment Home and Hospital	Yes	Yes
Design		
Same dimensions as the predicate	Yes	Yes
Offered in multiple sizes	Yes	Yes
Intended to be cleaned	Yes	Yes
Adapts to headgear	Yes	Yes
Separate Exhalation port / device required	Yes	Yes
Compatible with 22 mm tubing	Yes	Yes
Optional Foam Spacers	Yes	Yes
Optional Cushion Support Ring	Yes	Yes
Materials		
Cushion made of silicone	Yes	Yes
Cone and swivel elbow made of Polycarbonate	Yes	Yes
Exact materials as utilized in the predicate devices	Yes	Yes

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Attribute	EMS Nasal CPAP	Respironics Contour Nasal Mask K883825
Performance Standards / Specifications		
None required under Section 514	Yes	Yes
Differences between Other Legally Marketed Predicate Devices		

There are no significant differences between the intended device and the Respironics Silicone Contour Nasal CPAP mask approved under K883825.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 28 1998

Ms. Bonnie Holly
Engineered Medical Systems
8529 Zionsville Road
Indianapolis, IN 46268

Re: K972605
EMS Nasal CPAP Mask
Regulatory Class: II (two)
Product Code: 73 BZD
Dated: November 28, 1997
Received: December 2, 1997

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 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

SECTION 3

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: K972605

Device Name: EMS Nasal CPAP mask

Intended Use: The EMS Nasal CPAP mask and accessories (mask, spacers, mask support ring and headgear) are used with and attached to a positive pressure air source, CPAP or Bi-level equipment, and has the Indications for Use consistent with the Indications for Use of the equipment to which it is attached.

Environment of use: Hospital, sleep laboratories or home

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. Pugh

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K972605

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