2.1 510(k) Summary of Safety and Effectiveness

K023683

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

Non-Confidential Summary of Safety and Effectiveness

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October 31, 2002

Engineered Medical Systems
2055 Executive Dr.
Indianapolis, IN 46241

Tel (317) 246-5500
Fax (317) 246-5501

Official Contact:	Bonnie A. Holly – Quality Manager
Proprietary or Trade Name:	Multi-strap Full Face Mask
Common/Usual Name:	Full Face CPAP Mask
Classification Name:	Non-continuous ventilator (IPPB) accessory
Predicate Devices:	Caradyne – Whisperflow mask – K982283 Respironics – Spectrum Full Face Mask – K961915 ResMed – Sullivan Mirage Full Face Mask – K982530

Device Description:

The EMS Multi-strap Full Face mask covers both the nose and mouth and includes a non-rebreathing / anti-asphyxia valve, which is activated under flow / pressure from a CPAP or bi-level ventilator. It is open to ambient air when the ventilator is not ON allowing the patient to breath ambient air. It has a quick release mask harness system. It is single patient, multi-use.

Intended Use:

Indicated Use --	A patient interface accessory for use with CPAP and bi-level systems used in the treatment of adult OSA and / or ventilatory support. A minimum pressure of $\geq$ 3.0 cm H_2O at the mask is required.
Environment of Use --	Hospital, Sub-acute Institutions, Home

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General Technical Characteristics

Attribute	**EMS – Proposed device**
Indications for use	A patient interface accessory for use with CPAP and bi-level systems used in the treatment of adult OSA and / or ventilatory support. A minimum pressure of ≥ 3.0 cm H_2O at the mask is required.
Single patient, multi-use	Yes
Prescription	Yes
Intended population	Any patient
Intended Environment of Use	Hospital, Sub-acute Institutions, Home
Design	
Mask covers nose and mouth	Yes
Quick release mask harness	Yes
Non-rebreathing / anti-asphyxia valve	Yes
Must be used with exhalation valve in circuit	Yes
Open to ambient when ventilator off	Yes
Valve opens at ≥ 3 cm H_2O	Yes
Can be cleaned	Yes
Materials	
Mask cone and Elbow - PC	Yes
Mask cushion - PVC	Yes
Flap valve - Silicone	Yes
Performance Standards	
None under Section 514	Yes

Differences between Other Legally Marketed Predicate Devices

The data within the submission demonstrates that the proposed devices when compared to the predicate devices are safe and effective and are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 1 2003

Engineered Medical Systems, Inc.
C/O Mr. Paul Dryden
Regulatory Consultant
Promedic, Inc.
6329 West Waterview Court
McCordsville, Indiana 46055-9501

Re: K023683
Trade/Device Name: Multi-Strap Full Face Mask
Regulation Number: 868.5905
Regulation Name: Non-Continuous Ventilator
Regulatory Class: II
Product Code: BZD
Dated: October 8, 2003
Received: October 9, 2003

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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.

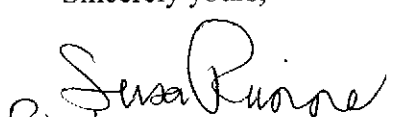
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

2.3 Indications for Use

510(k) Number: K023683 (To be assigned)

Device Name: Multi-strap Full Face Mask

Intended Use: A patient interface accessory for use with CPAP and bi-level systems used in the treatment of adult OSA and / or ventilatory support.

A minimum pressure of $\geq$ 3.0 cm H_2O at the mask is required.

Single patient, multi-use

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K023683

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