JUN 3 0 2004

K041309

510(k) SUMMARY OF SAFETY & EFFECTIVENESS

May 13, 2004

Marquest Medical Products, Inc.
11039 East Lansing Circle
Englewood, CO 80112
(A division of Vital Signs, Inc.)

Tel – (303) 790-4835 ext. 412
Fax – (303) 799-0210

Official Contact:	Tom Dielmann, Vice President of RA/QA
Proprietary or Trade Name:	***iMask ™ (K041309)***
Common/Usual Name:	Nasal CPAP Mask
Classification Name:	73 BZD - Ventilator, Non-Continuous (Respirator) Subsection 868.5905
Intended Device:	CPAP Nasal Mask
Predicate Device:	SleepNet Corporation IQ™ Mask – K993269
Device Description:	A nasal CPAP mask that is used with positive airway pressure equipment recommended by a physician, sleep technician, or respiratory therapist.
Indicated Use:	This device is intended to be used with positive airway pressure devices operating at or above 4cmH_2O for the treatment of adult obstructive sleep apnea.
Targeted Population:	Adult population using a continuous positive airway pressure device.
Environment of Use:	Home, hospital, or sleep lab.

510(k) SUMMARY OF SAFETY & EFFECTIVENESS
(continued)

Attribute	Marquest/VSI iMask™	SleepNet IQ™ Mask K993269
Use		
Intended for use in respiratory therapy	Yes	Yes
Intended to be used with any CPAP device	Yes	Yes
Indicated for single patient use In home, hospital, or sleep lab	Yes	Yes
Indicated for use with adult cases	Yes	Yes
Design/Performance		
Comfortable face cushion	Yes	Yes
15mm swivel elbow connection	Yes	Yes
3-point headstrap connection	Yes	Yes
Adequate venting to minimize rebreathing CO_2	Yes	Yes
Vent design to minimize noise	Yes	Yes
No latex materials	Yes	Yes
No sharp edges	Yes	Yes
Mask is lightweight	Yes – 64 grams	Yes – 60 grams
Polybag packaging (clean non-sterile)	Yes	Yes

510(k) SUMMARY OF SAFETY & EFFECTIVENESS
(continued)

Attribute	Marquest/VSI iMask™	SleepNet IQ™ Mask
Materials		
Polyurethane Housing	Yes	Yes
Polycarbonate & Acetal Copolymer 15mm Swivel Elbow	Yes	Yes
Wire Insert Molded Into Mask Housing	Yes	Yes
Soft Facial Contact Cushion	Yes	Yes
Polycarbonate 3-Point Headstrap Bracket	Yes	Yes
Airway & direct contact component materials meet USP Class VI standards	Yes	Yes
Performance Testing		
Meets ASTM F1054-87 & ISO 5356-1 Standards	Yes	Yes
Meets ISO 17510-2:2003 Standard	Yes	Yes
Minimum 12 lpm @ 4 cm H_2O Mask Leakage To Prevent CO Rebreathing	Yes	Yes

Differences

The only difference between the iMask™ and the predicate device is the face cushion material. The iMask™ cushion material was submitted for required biocompatability testing (cytotoxicity, sensitization, and irritation/intracutaneous reactivity). The mask materials have passed the USP Class VI tests (see attachment).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Vital Signs, Incorporated
C/O Mr. Thomas Dielmann
Vice President, Quality and Regulatory Affairs
Marquest Medical Products, Incorporated
11039 East Lansing Circle
Englewood, Colorado 80112

Re: K041309
Trade/Device Name: ***iMask*** ™ Nasal CPAP Mask
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator
Regulatory Class: II
Product Code: BZD
Dated: May 14, 2004
Received: May 17, 2004

Dear Mr. Dielmann:

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) 594-4618. 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

INDICATIONS FOR USE

510(k) Number: **K041309**

Device Name: *iMask* ™ Nasal CPAP Mask

Indications For Use: This device is intended to be used with positive airway pressure devices operating at or above 4cmH_2O for the treatment of adult obstructive sleep apnea.

Prescription Use __X__ AND/OR Over-The-Counter Use ____
(per 21 CFR 801 Subpart D)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K041309