

Non-Confidential Summary of Safety and Effectiveness

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26-Sept-07

Galemed Corporation
87, Li-gong, 2nd Road
Wu-jia, I-Lan, 268, Taiwan

Tel – 011-3-990-8618

Official Contact: Thomas Loescher

Proprietary or Trade Name: CPAP masks

Common/Usual Name: Patient interface for use with CPAP systems

Classification Name: Ventilator, non-continuous (respirator), accessory
BZD – 868.5905

Device: CPAP masks

Predicate Devices: Hsiner Co., Ltd. – K063268

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Device Description:

The proposed CPAP masks incorporate a number of features, which are designed to maximize seal and comfort, and maintain the mask in the correct position throughout use.

- Full face and Nasal style
- Integral anti-asphyxia valve
- Headgear for attachment
- Single use disposable and Single patient, multi-use

Indications for Use: The GaleMed CPAP masks are intended to be used in a home, hospital or institutional environment for patients who have been prescribed CPAP/VPAP therapy. This device is intended to be used under the specific direction of a physician. Disposable and Single patient, multi-use styles.

Patient Population: Adults with OSA

Environment of Use: Hospitals, Home, sub-acute care settings

Contraindications: None

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Comparative table:

Features	Predicate Hsiner K063268	Proposed Device
Indications for use	The Hsiner CPAP masks are intended to be used in a home, hospital or institutional environment for patients who have been prescribed CPAP/VPAP therapy. This device is intended to be used under the specific direction of a physician. Disposable and Single patient, multi-use styles.	Identical
Environment of Use	Home, Hospital, Sub-acute Institutions	Same
Patient Population	Adult	Same
Contraindications	None	None
Single patient, Multi-use	Yes	Yes
Components	Headgear Anti-asphyxia valve	Headgear Anti-asphyxia valve
Anti-asphyxia valve	Yes	Yes
Materials	Polycarbonate Silicone	Identical K063268
Comparative testing for safety and efficacy	Flow vs. Leak / Pressure Dead space	Identical

Differences Between Other Legally Marketed Predicate Devices:

The proposed device is identical to the predicate device, K063268.

There are no differences that affect the safety or effectiveness of the intended device as compared to the predicate devices.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Galemed Corporation
C/O Mr. Paul Dryden
President
ProMedic, Incorporated
3460 Pointe Creek Court, # 102
Bonita Springs, Florida 34134-2015

Re: K072755
Trade/Device Name: CPAP Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: September 26, 2007
Received: September 27, 2007

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.

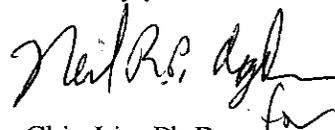
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0115. 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/industry/support/index.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 Statement

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

Device Name: CPAP mask

Indications for Use: The GaleMed CPAP masks are intended to be used in a home, hospital or institutional environment for patients who have been prescribed CPAP/VPAP therapy. This device is intended to be used under the specific direction of a physician. Disposable and Single patient, multi-use styles.

Prescription Use XX
(Part 21 CFR 801 Subpart D)

or

Over-the-counter use ___
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number: K072755