K063268

8. 510(k) Summary

In accordance with 21 CFR section 807.92 Hsiner is submitting the following 510(k) summary.

8.1. Submitter Information

Hsiner Company, LTD
No. 13, Tyan Shin St., Taya Hsiang
Taichung Hsien, Taiwan, ROC

Phone: +886-4-25664306

FEB 2 3 2007

Registration No.: 3003862188
Owner/Operator No.: 9053474

8.2. Name of Device

Proprietary Name:	CPAP/VPAP Masks
Common Name:	CPAP Mask
Classification Name:	Noncontinuous ventilator (IPPB)
Product Code:	BZD
Regulation Number:	868.5905
Device Class	2

8.3. Substantially equivalent to:

- Respironics ComfortFull Full-Face CPAP Mask (K002465, K961915)
- Respironics Comfort Select Nasal CPAP Mask (K000705, K991648)

8.4. Description of the device

The Hsiner CPAP/VPAP Masks is used to administer various aerosol treatments in both the homecare and hospital settings.

8.5. Intended Use of the Device

The Hsiner CPAP/VPAP masks are intended to be use in a home, hospital or Institutional environments for patients who have been prescribed CPAP/VPAP therapy. This device is intended to be use under the specific direction of a physician.

8.6. Comparison to Predicate Devices

The Hsiner CPAP/VPAP Masks is equivalent in design, materials and performance to the Predicate devices. All the predicate devices utilize the same principles of operation and have the same intended use

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Hsiner Company, Limited
C/O Mr. Tom Shanks
Principal
MDVentures
29201 Via Norte
Temecula, California 92591

FEB 23 2007

Re: K063268
Trade/Device Name: Hsiner CPAP/VPAP Masks
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: February 5, 2007
Received: February 8, 2007

Dear Mr. Shanks:

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.

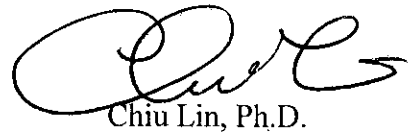
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0120. 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

510(k) Number (K052811):

Device Name: Hsiner CPAP/VPAP Masks

Indications for Use:

The Hsiner CPAP/VPAP masks are intended to be use in a home, hospital or Institutional environments for patients who have been prescribed CPAP/VPAP therapy. This device is intended to be use under the specific direction of a physician.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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