JUL 16 2012

13. 510(k) Summary K120920

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

13.1. Date: 07/11/2012

13.2. Submitter Information

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

Phone: +886-4-25664306

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

13.3. Name of Device

Proprietary Names:

1. Hsiner Pediatric CPAP Silicone Nasal Masks
2. Hsiner Nasal Pillow Mask

Common Name: CPAP Mask
Classification Name: Noncontinuous ventilator (IPPB)

Product Code: BZD

Regulation Number: 868.5905

Device Class 2

13.4. Substantially equivalent to:

This submission compares the Hsiner extension devices to Hsiner's CPAP/VPAP Masks (K K063268) in addition to the following predicate devices;

1. Hsiner Pediatric CPAP Silicone Nasal Mask to the Hsiner CPAP/VPAP Nasal Masks (K063268)and ResMed's Mirage Kidsta Mask (K060105) and ResMeds PixiTM Pediatric Mask (K102224),
2. Hsiner Nasal Pillow Mask to Repironics' GoLife Nasal Mask (K102502).

13.5. Comparison to Predicate Devices

There are no technological differences between these devices.

13.5.1. Design, Materials and Intended Use

The Hsiner CPAP Silicone Nasal Mask and Hsiner Nasal Pillow Mask devices, accessories, attachments, principles of operation and materials are all essentially equivalent to predicate devices already cleared by FDA. The Hsiner, ResMed and Respironics devices operate on the same principles and have the same intended use.

13.6. Description of the device

Hsiner's Pediatric CPAP Silicone Nasal Mask and Hsiner's Nasal Pillow Mask are both product line extensions to their existing line of CPAP interface devices for the application of CPAP/VPAP therapy.

13.7. Intended Use of the Device

1. **Hsiner Pediatric CPAP Silicone Nasal Masks:** - - The Hsiner Pediatric CPAP Silicone Nasal Mask is intended to be use with patients (> 30 kg) who have been prescribed CPAP/VPAP therapy in a home, hospital or institutional environments. This device is intended to be use under the specific direction of a physician.
2. **Hsiner Nasal Pillow Mask:** The Hsiner Nasal Pillow Mask is intended to be use patients (> 30 kg) who have been prescribed CPAP/VPAP therapy in a home, hospital or institutional environments. This device is intended to be use under the specific direction of a physician.

13.8. Clinical-Performance Evaluations

No clinical test was performed for this device

13.9. Performance Evaluation

The performance test protocols for Hsiner's line extensions follow appropriate sections of ISO 17510-2 (2007): "Sleep apnea breathing therapy—Part 2: Masks and application accessories."

1. Hsiner's Pediatric CPAP Silicone Nasal Mask was found to be well below the resistance to flow and CO_2 rebreathing requirement identified in ISO 17510-2.
2. Hsiner's Nasal Pillow Mask was found to be well below the resistance to flow and CO_2 rebreathing requirement identified in ISO 17510-2.

13.10. Conclusion

- Performance evaluation concludes that all the devices meet the requirements associated with ISO 17510-2 "Sleep apnea breathing therapy—Part 2: Masks and application accessories" and that there are no significant differences in resistance to flow and CO_2 rebreathing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Hsiner Company
C/O Mr. Tom Shanks
MD Ventures
29201 Via Norte
Temecula, California 92591

JUL 16 2012

Re: K120920
Trade/Device Name: Hsiner CPAP Nasal Pillow Mask, Hsiner Pediatric CPAP Silicone Nasal Masks
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: June 29, 2012
Received: July 2, 2012

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Anthony D. Watson, B.S., M.S., M.B.A.
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 :

Device Name: Hsiner CPAP Nasal Pillow Mask

Indications for Use:

The Hsiner Nasal Pillow Mask is intended to be use patients (> 30 kg) who have been prescribed CPAP/VPAP therapy in a home, hospital or institutional environments. This device is intended to be use under the specific direction of a physician.

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

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

510(k) Number: K120920

Indications for Use

510(k) Number:

Device Name: Hsiner Pediatric CPAP Silicone Nasal Masks

Indications for Use:

The Hsiner Pediatric CPAP Silicone Nasal Mask is intended to be use with patients (> 30 kg) who have been prescribed CPAP/VPAP therapy in a home, hospital or institutional environments. This device is intended to be use under the specific direction of a physician.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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) Page 1 of 1

L Schultz

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

510(k) Number: K120920