E1 - K102120_ Summary_052511 AUG 1 2 2011

8. 510(k) Summary

Date: 03 November 2010

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

8.1. Submitter Information

Hsiner Company, LTD
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Registration No.: 3003862188
Owner/Operator No.: 9053474

8.2. Name of Device

Proprietary Name: NIPPV Masks
Common Name: Non-invasive Ventilation Mask
Classification Name: Ventilator, Continuous, Facility Use

Product Code: CBK

Regulation Number: 868.5895

Device Class: 2

8.3. Description of the device

Hsiner's NIPPV Masks are intended to provide a patient interface between a conventional mechanical ventilator system and the patient for applications of non-invasive ventilation. The connection to the ventilator utilizes standard 22mm conical connections complying with ISO 5356-1. The interface with the patient's facial contours utilizes a soft, pliable seal that ensures that a good seal is achieved to deliver the pressurized gasses with minimal unintentional leakage. Unintentional gas leak around the face is minimized by the shaping of the mask base to improve the closeness of fit to the skin. Soft, elastic headgear insures a tight comfortable fit against the face.

The Hsiner NIPPV Masks are modifications to their CPAP/VPAP Masks (K063268). These masks differ from the CPAP/VPAP mask only in that the vents and anti-asphyxiation valves have been removed.

8.4. Substantially equivalent to:

- Hsiner's CPAP/VPAP Masks (K063268)
- Fisher Paykel RT041 Hospital Full Face Mask Non Vented (K083122)

8.5. Intended Use of the Device

The Hsiner NIPPV masks provide a patient interface for application of noninvasive ventilation with ventilators with adequate alarms and safety systems to protect the patient in the event for ventilator failure. These masks are intended for use with spontaneous breathing adult patients (> 30 kg) to administer CPAP or positive pressure ventilation for treatment of respiratory failure.

respiratory insufficiency, or obstructive sleep apnea who are appropriate candidates for noninvasive ventilation, in the hospital/institutional environment.

Hsiner's Nasal Mask is intended for patients that have trouble tolerating their full face versions

8.6. Clinical-Performance Evaluations

No clinical test was performed for this device

8.7. Comparison to Predicate Devices

8.7.1. Design, Materials and Intended Use

The Hsiner NIPPV masks are equivalent in design; materials and performance to the Fisher Paykel's RT41 NIV face mask (K083122) and Hsiner's CPAP/VPAP mask. The Hsiner and Fisher Paykel devices operate on the same principles and have the same intended use.

8.8. Performance Evaluation

The performance test protocols for Hsiner's NIPPV Masks follow those section of FDA's July 1995 guidance document "Draft Reviewer Guidance for Ventilators" applicable to masks used with ventilators and include testing from both ASTM 1100-90 "Standard Specification for Ventilators Intended for Use in Critical Care" and ISO 17510-2 (2007): "Sleep apnea breathing therapy—Part 2: Masks and application accessories."

- Resistance to flow showed negligible difference between all masks.
- Exhaust flow showed negligible differences at low pressure settings with Hsiner's NIPPV and CPA/VPAP masks showing higher flows at higher pressure levels than the Fisher Paykel RT041.
- CO_2 Rebreathing showed negligible differences for the Hsiner NIPPV and Fisher Paykel masks. As would be expected Hsiner"s CPAP/VPAP showed slightly lower $EtCO_2$ levels.
- Fraction of Inspired Oxygen (FIO2) showed slightly higher over all FIO_2 percentages for the Fisher Paykel masks. All FIO_2 values were significantly lower with added 20 LPM leaks compared to identical configurations without leak. As expected decreasing therapeutic pressure results in higher FIO_2 percentages. Increasing supplemental O_2 flow rates resulted in significant increases in FIO_2.
- Swivel leakage was notably higher for Hsiner NIPPV masks compared to the Fisher Paykel RT041 Mask.

8.8.1. Conclusion:

Performance evaluation concludes that there are negligible differences resistance and exhaust flow. The Hsiner masks show slightly better $EtCO_2$ and slightly lower FIO2 values than the Fisher Paykel masks.

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, Limited
% Mr. Tom Shanks
MD Ventures
29201 Via Norte
Temecula, California 92591

AUG 12 2011

Re: K102120
Trade/Device Name: Hsiner NIPPV Masks
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: July 30, 2011
Received: August 11, 2011

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

cc: DMC - 2 copies
ODE Division/Branch ARDB – Sugato De
8/12/11-EFW

C1 - K102120_Indications for Use_052511

Hsiner Company NIPPV Masks 510(k) Submission

Indications for Use

510(k) Number

Device Name: Hsiner NIPPV Masks

Indications for Use:

The Hsiner NIPPV masks provide a patient interface for application of noninvasive ventilation with ventilators with adequate alarms and safety systems to protect the patient in the event for ventilator failure. These masks are intended for use with spontaneously breathing adult patients (> 30 kg) with respiratory insufficiency or respiratory failure suitable for noninvasive pressure support ventilation treatment in the hospital/institutional environment (including but not limited to moderate or severe dyspnea, elevated respiratory rates, labored breathing, or paradoxical breathing).

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)

Nayan Patel for L Schultheis

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

510(k) Number: K102120