

DEC 21 2005

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

Registration No.: 3003862188

Owner/Operator No.: 9053474

8.2. Preparer of Submission and Contact for Information

MDVentures

Tom Shanks* – Principal
29201 Via Norte
Temecula, CA 92591

Phone: (951) 506-2674

FAX: (951) 506-3040

E-mail: tom@mdventures

*Submission contact for correspondence and additional information

8.3. Name of Device

Proprietary Name: Jet Nebulizer
Common Name: Nebulizer
Classification Name: Nebulizer (direct patient interface)
Product Code: CAF
Regulation Number: 868.5630
Device Class 2

8.4. Substantially equivalent to:

- Allegiance Misty-Neb (K883964).
- Salter Labs Nebulizer (K884947)
- Hudson RCI Micro Mist (K930525)

8.5. Description of the device

The Hsiner Jet Nebulizer is used to administer various aerosol treatments in both the homecare and hospital settings. This device is intended to only be use with FDA-approved drugs upon the

Hsiner Company Jet Nebulizer 510(k) Submission

specific direction of a physician. This device is not used specific drug nor is it distributed with such drugs.

The nebulizer sprays respiratory size aerosolized liquids into gasses that are delivered directly to the patient for breathing. The nebulizer operates on a compressed gas source which draws liquids from a refillable Jar by the venturi principle and aerosolizes it into respirable particles by impaction and baffling.

8.6. Intended Use of the Device

The Hsiner Jet Nebulizer is used to administer various aerosol treatments in both the homecare and hospital settings. This device is intended for use only with FDA-approved drugs upon the specific direction by a physician. Its use is indicated whenever a physician or healthcare professional administers or prescribes medical aerosol products to a patient using a Small Volume Nebulizer.

8.7. Comparison to Predicate Devices

The Hsiner Jet Nebulizer 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.

Performance testing was conducted invitro using a Cascade Impactor method according to the "Reviewer Guidance for Nebulizers Metered Dose Inhalers, Spacers and Actuators (10-01-93)." The following characteristics were determined for each Nebulizer:

- Mass Mean Aerodynamic Diameter (MMAD)
- Geometric Standard Deviation (GSD)
- Respirable Fraction
- Respirable Mass
- Treatment Time
- Operating pressures

The mean Mass Median Aerodynamic Diameter (MMAD), Geometric Standard Deviation (GSD), respirable fraction (% mass between 0.5 and 5 microns), total mass of medication delivered, respirable mass (mass of drug between 0.5 and 5 microns), and treatment time for the Hsiner Jet Nebulizer was not found to not be significantly different than the predicate device for any of the drugs tested.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 2005

Hsiner Company Limited
Mr. Tom Shanks
Principal
Mdventures
29201 Via Norte
Temecula, California 92591

Re: K052811
Trade/Device Name: Hsiner Jet Nebulizer
Regulation Number: 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: September 29, 2005
Received: October 4, 2005

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.

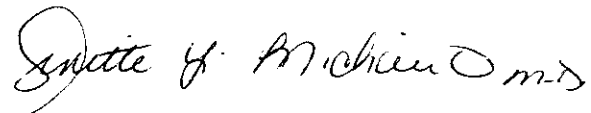
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Hsiner Company Jet Nebulizer 510(k) Submission

Indications for Use

510(k) Number (K052811):

Device Name: Hsiner Jet Nebulizer

Indications for Use:

The Hsiner Jet Nebulizer is used to administer various aerosol treatments to adult and pediatric patients in both the homecare and hospital settings. This device is intended for use only with FDA-approved drugs upon the specific direction by a physician. Its use is indicated whenever a physician or healthcare professional administers or prescribes medical aerosol products to a patient using a Small Volume Nebulizer.

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)



K052811

Page 1 of 1