K070948

6. 510(k) Summary

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

6.1. Submitter Information

Hsiner Company, LTD
No.312, Jhongshan Rd., Shengang Township,
Taichung County 429
Taiwan, ROC

Phone: +86-4-25152480

APR 25 2007

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

6.2. Name of Device

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

6.3. Substantially equivalent to:

- Hsiner Jet Nebulizer (K052811)

6.4. Description of the device

The Hsiner Nebulizer Bottle 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 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.

6.5. Intended Use of the Device

The Hsiner Nebulizer Bottle 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.

6.6. Comparison to Predicate Devices

The Hsiner Nebulizer Bottle is equivalent in design, materials and performance to the Hsiner Jet Nebulizer and utilizes the same principles of operation and has the same intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

APR 25 2007

Re: K070948
Trade/Device Name: Hsiner Nebulizer Bottle
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: April 1, 2007
Received: April 4, 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 (240) 276-3150 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 (K070948**):**

Device Name: Hsiner Nebulizer Bottle

Indications for Use:

The Hsiner Nebulizer Bottle 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___ 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)

[illegible]

[illegible] of Anesthesiology, General Hospital,
[illegible]ction Control, Dental Devices

510(k) Number K070948