



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

April 17, 2013

Ms. Gloria Chen
General Manager
Headstar Medical Products Company, Limited
9F, Number 8, Sec 1
Chung-Shan Road, Hsin-Chang
City, Taipei County
China (Taiwan) 242

Re: K121770

Trade/Device Name: Headstar Medical Small Volume Jet Nebulizer
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: January 25, 2013
Received: March 11, 2013

Dear Ms. Chen:

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 contact 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

**Kwame O.
Ulmer - S**

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K121770

Device Name: HEADSTAR MEDICAL SMALL VOLUME JET NEBULIZER

Indications for Use:

The Headstar medical Small Volume Jet nebulizer creates respiratory mist out of the drug and is used to administer various aerosol treatments to adult and pediatric patients in homecare and hospital environments. It is not intended for transport use.

Based on practical measurement and comparison, Headstar Medical Small Volume Jet Nebulizer is intended for following populations:

HP-2557 Nebulizer with child face mask: 2~9 years old pediatric patients

HP-2558 Nebulizer with adult face mask: for adult patients

HP-2290 Nebulizer with mouth piece & O2 tubing: pediatric over 5 years and adult patients

HP-2291 Nebulizer with mouth/T piece & hose/O2 tubing: pediatric over 5 years and adult patients

The nebulizer operates on a compressed gas source which draws liquids from a refillable jar and aerosolizes it into respirable particles by impaction and baffling. Its use is indicated whenever a healthcare professional administers or prescribes medical aerosol products to a patient using a small volume nebulizer. It can be packaged with optional accessories; i.e.; oxygen tubing, mouthpiece, T piece, hose and face mask. Nebulizer bottle, T piece and mouthpiece are single patient re-use devices; while other accessories are single use/disposable devices. Headstar Medical small volume jet nebulizer is packed non-sterile in a polyethylene bag.

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 OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K121770

Albert E. Moyal  c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=130 0059331, cn=Albert E. Moyal -S 2013.04.16 11:28:41 -04'00' (for LS)

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

510(k) Number: K121770
Page 1 of 1