DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 3 0 2004

Guan Hong Enterprise Company Limited
C/O Ms. Jennifer Reich
3892 South America West Trail
Flaggstaff, Arizona 86001

Re: K041079
Trade/Device Name: Guan Hong Model #AC103/DR 103 Ultrasonic Nebulizer
Regulation Number: 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: August 30, 2004
Received: August 7, 2004

Dear Ms. Reich:

This letter corrects our substantially equivalent letter of September 28, 2004 regarding the company name.

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 (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.

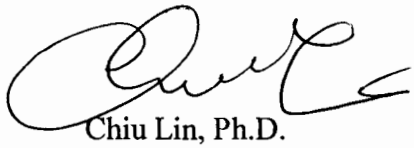
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 continue 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) 276-0115. 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/dsma/dsmamain.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 (if known): K041079

Device Name: **GUAN HONG Model # AC103 / DR 103 Ultrasonic Nebulizer**
**GUAN HONG ENTERPRISE CO.,LTD.**

Indications For Use:

The **GUAN HONG Model# AC103/DR 103 Ultrasonic Nebulizer** is an ultrasonic nebulizer that is intended for use in the treatment of asthma, COPD and other respiratory ailments in which an aerosolized medication is required during therapy. The **GUAN HONG Model# AC103/DR 103 Ultrasonic Nebulizer** is not intended for use with Pentamidine. It is intended for single patient use.

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

510(k) Number: K041079

Prescription Use V AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K041079

# 510(K) SUMMARY

SEP 2 8 2004



This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

1.0 Submitter's Name: **GUAN HONG ENTERPRISE CO.,LTD.**


Address: No.17 Hsin Ren Rd.,An-Ping Industrial District, Tainan, Taiwan, R.O.C.

Phone: 001-886-6-2614191

Fax: 001-886-2-2637008

Contact: Mr. James Lin, General Manager


2.0 Device Name: **GUAN HONG Ultrasonic Nebulizer**
Model No.:
MH-AC 103 (/or AC 103) Portable Ultrasonic Nebulizer
MH-DR 103 (/or DR 103) Ultrasonic Nebulizer

3.0 Classification: Class II

4.0 Predicate Device: **GUAN HONG Model# MH-AC103 / MH-DR 103 Ultrasonic Nebulizer** has similar general design with **Mabis NB-02 Ultrasonic Nebulizer (K990506)** marketed by **MABIS HEALTHCARE, INC.**

5.0 Device Description: GUAN HONG Ultrasonic Nebulizer (Model MH-AC 103 & MH-DR 103) is designed to spray liquids in aerosol form into gases directly to the patient for use by the adult and pediatric population.

The Ultrasonic Nebulizer units contains a piezoelectric crystal that generate ultrasonic waves which are transmitted through buffer water to medication cap and convert the liquid medication into an aerosol. The Nebulizer medication cap is designed for single-patient use and holds up to 5ml of medication for Model # AC 103 , 8 ml for Model # DR 103.

Inhalation can be made through nose or mouth. Attachments that are used during the nebulization process include MOUTHPIECE, ADULT MASK; PEDIATRIC MASK, NOSE FORK , CONNECTOR, CORRUGATED TUBE.

6.0 Indication for Use: The **GUAN HONG Model# AC103/DR 103 Ultrasonic Nebulizer** is an ultrasonic nebulizer that is intended for use in the treatment of asthma, COPD and other respiratory ailments in which an aerosolized medication is required during therapy. The **GUAN HONG Model# AC103/DR 103 Ultrasonic Nebulizer** is not intended for use with Pentamidine. It is intended for single patient use.

7.0 Performance Summary: In terms of operating specification, Safety & EMC requirements, the device conforms to applicable standards included IEC 60601-1 , IEC 60601-1-2 and NEBULIZER CHARACTERIZATION STUDY , ISO 10993 requirements. A comparison study with device that use auscultatory method was performed to validate the performance of the **GUAN HONG Model# MH-AC103 / MH-DR 103 Ultrasonic Nebulizer.** The comparison study demonstrated that the clinical repeatability of **GUAN HONG Model# MH-AC103 / MH-DR 103 Ultrasonic Nebulizer** is statistically and clinically acceptable.

8. Conclusions:

The **GUAN HONG Model# MH-AC103 / MH-DR 103 Ultrasonic Nebulizer** have the same intended use and similar technological characteristics as **Mabis NB-02 Ultrasonic Nebulizer (K990506)** marketed by **MABIS HEALTHCARE, INC.**. Moreover, bench testing contained in this submission and clinical testing supplied demonstrate that any differences in their technological characteristics do not raise and new questions of safety or effectiveness. Thus, the **GUAN HONG Model# MH-AC103 / MH-DR 103 Ultrasonic Nebulizer** is substantially equivalent to the predicate devices.