K081738

SEP 1 7 2008

510(k) Summary – Health and Life Model HL100 Ultrasonic Nebulizer System

0.0 MANUFACTURER IDENTIFICATION

Manufacturer:	Health and Life Corporation
Address:	9F, No. 186, Jian-Yi Rd
City, State:	Chung Ho City, Taipei Hsien, Taiwan

1.0 PRODUCT NAME

Common or usual name or classification name:	**Nebulizer (Direct Patient Interface)**
Trade or proprietary or model name:	**HL100 Ultrasonic Nebulizer System**

2.0 PRODUCT CLASSIFICATION

Device Class:	**II**
Product Code:	**73 CAF**
C.F.R. Section:	
Classification Panel:	**Anesthesiology**

3.0 PREDICATE DEVICE

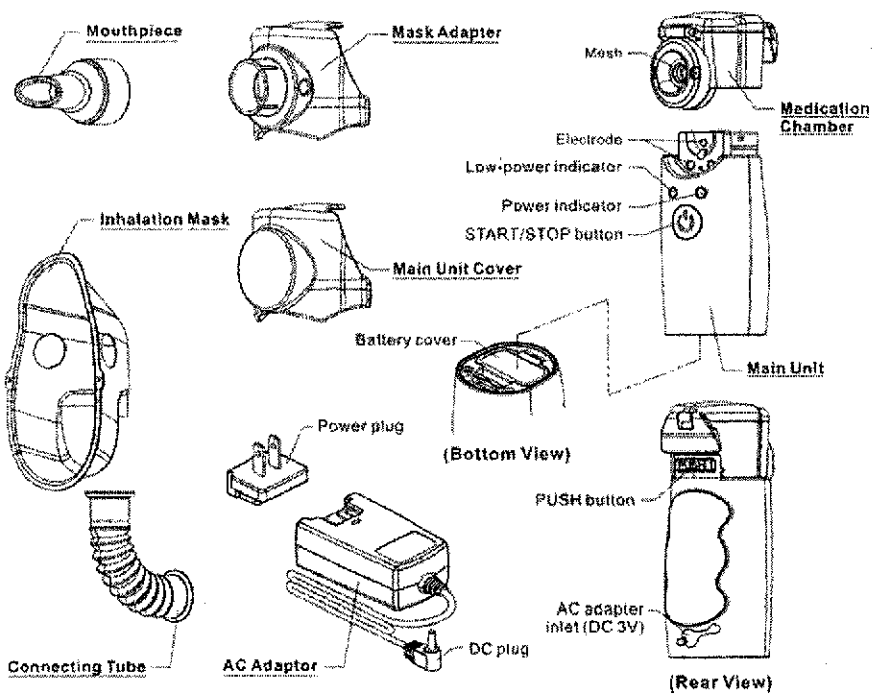
Omron Model NE-U22V MircroAir Nebulizer (K062263)

4.0 DEVICE DESCRIPTION

The Health and Life Model HL100 is a mesh screen ultrasonic nebulizer that operates in an identical fashion as other mesh screen ultrasonic nebulizers, including the referenced predicate device. The device creates aerosols of liquid medication by ejection of droplets from a mesh (aperture plate) vibrated at ultrasonic frequencies. As with other mesh screen ultrasonic nebulizers, the mesh is caused to vibrate by fluidic contact with a ultrasonic piezoelectric member that is energized by application of a high frequency alternating voltage.

The HL100 Ultrasonic Nebulizer System consists primarily of a Main Unit and a Medication Chamber. The Main Unit and the Medication Chamber are single patient re-usable. The Main Unit contains all control circuitry and is powered by a cable connecting to a 115 VAC power source with the AC adapter or two AA alkaline batteries. No medication comes into contact with the Main Unit, only the Medication Chamber. The patient interface consists of a mouthpiece or an optional mask. When the device is turned on, the ultrasonic piezoelectric member vibrates, causing the mesh to vibrate. Liquid medication in the reservoir is caused to be aerosolized by

the vibrating mesh into the patient interface where the aerosol particles can be inhaled by the patient.



5.0 INTENDED USE

The HL100 Ultrasonic Nebulizer System utillizes the state-of-the-art elecctrospray technology that sprays liquid medication in aerosol form and deliveries it directly to the adult and pediatric patients who suffer from asthma, Chronic Obstructive Pulmonary Disease (COPD) such as emphysema and chronic bronchitis, or other respiratory diseases that are characterized by obstruction to air flow for breathing.

6.0 COMPARISON TO PREDICATE DEVICE

The Health and Life Model HL100 Ultrasonic Nebulizer System is substantially equivalent to the Omron Model NE-U22V MircroAir Nebulizer (K062263). Non-clinical tests have been performed comparing the HL100 Ultrasonic Nebulizer System to the predicate device and have shown that the performance of the HL100 Ultrasonic Nebulizer System is substantially equivalent to the performance of the predicate device. No clinical tests were conducted

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 7 2008

Health & Life Company, Limited
C/O Mr. Samuel Piper
President/Chief Executive Officer
Piper Medical, Incorporated
P.O. Box 993
Carmichael, California 95609

Re: K081738
Trade/Device Name: HL100 Ultrasonic Nebulizer System
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: June 17, 2008
Received: June 19, 2008

Dear Mr. Piper:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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

Enclosures

Indications for Use

510(k) Number (if known):

Device Name: HL100 Ultrasonic Nebulizer System

Indications For Use: The HL100 Ultrasonic Nebulizer System utillizes the state-of-the-art elecctrospray technology that sprays liquid medication in aerosol form and deliveries it directly to the adult and pediatric patients who suffer from asthma, Chronic Obstructive Pulmonary Disease (COPD) such as emphysema and chronic bronchitis, or other respiratory diseases that are characterized by obstruction to air flow for breathing.

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)

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

510(k) Number: K081738