510(K) SUMMARY

FEB 2 1 2007

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92, and the relevant 510(K) submission guidance.

The assigned 510(K) number is: K062952

1. **Submitter's Identifications:**

Mr. Mok Chi Wing
Choice Smart Health Care Company Limited.
RM 1901, CC WU BUILDING,
302 HENNESSY ROAD,
WANCHAI
Hong Kong
Phone (852) 28934110
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Date of Preparation: April 14, 2006

2. **Name of the device:**
   C300 Series Air Nebulizer Compressor

Common Name:	Nebulizer Compressor
Classification Name:	Compressor, Air, Portable

3. **Predicate Device Information and Substantial Equivalence:**
   Model IRC 1001 Aerosol Compressor, Invacare Corp., K992643
   3655 Series DeVilbiss Pulmo-Aide Compact Compressor, Sunrise Medical HHG, Inc., K020932

4. **Device Description:**
   The C300 Series Air Nebulizer Compressor is AC line powered (120V) device. Only the compressor unit is supplied by the sponsor. Other accessories which are directly contacted the patients are not included in this application. These accessories include Air Tubing, Nebulizer, Adaptor, Flexi Tubing, and Mouthpiece. Suggest selecting those accessories which have already obtained 510(K) clearance and are available on the

market.

The compressor is driven with a motor inside, and is AC line powered (120V) with an on/off switch. Inside of the compressor also have an inlet filter and a filter cover. Outside is a plastic body (including a top cover, a left cover, and a right cover).

5. **Intended Use:**
   C300 Series Air Nebulizer Compressor is intended to provide a source of compressed air to a pneumatic nebulizer for the generation of aerosolized medications for inhalation by a patient, based on a physicians' prescription.

6. **Comparison to the 510(k) Cleared Device (Predicate Device):**
   The C300 Series Air Nebulizer Compressor has the same intended use and technological characteristics as the cleared device of Model IRC 1001 Aerosol Compressor (K992643) and DeVilbiss Pulmo-Aide Compact Compressor (K020932). Although there are slight differences between the new device and the legally marketed one, these differences do not affect the safety, performance of the subject device. So the new device is substantial equivalent to the selected predicate device.

7. **Discussion of Non-Clinical Tests Performed Determination of Substantial Equivalence are as follows:**
   The Compressor is compliance to applicable voluntary standards includes IEC 60601-1, IEC 60601-1-2. VOC and PM 2.5 testing also shows the compressor is compliance to relevant EPA standards.

8. **Conclusions:**
   The C300 Series Air Nebulizer Compressor is substantial equivalent to predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2007

Choice Smart Health Care Company, Limited
C/O Ms. Michelle S. Lee
Reviewer
Underwriters Laboratories, Incorporated
2600 N.W. Lake Road
Camas, Washington 98607-8542

Re: K062952
Trade/Device Name: C300 Series Air Nebulizer Compressor
Regulation Number: 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: February 9, 2007
Received: February 13, 2007

Dear Ms. Lee:

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.

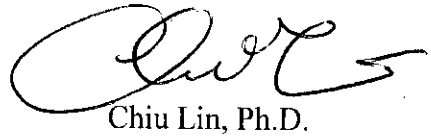
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Indication for Use Statement

510(k) Number (if known):

Device name: C300 Series Air Nebulizer Compressor

Indications for Use:

C300 Series Air Nebulizer Compressor is an AC powered air compressor that provides a source of compressed air for home health care use. The compressor should be used with a pneumatic nebulizer to convert certain inhaled drugs into an aerosol form for inhalation by a patient. This device can be used by adult or pediatric patients.

Prescription Use __√__ OR Over-The-Counter Use____
(Per 21CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

K062952