K081508

AUG 27 2008

Shenyang Canta Medical TECH. Co., Ltd

Chapter III 510(k) Summary

As Required by CFR 807.92

The assigned 510(k) Number is: _____

1. Date Prepared: May 27, 2008

2. Sponsor Information

   Shenyang Canta Medical Tech. Co., Ltd
   No.127 Nujiang Street, Huanggu District
   Shenyang 110036, P.R.China

   Contact Person: Mr. Qiu Xiao, Quality Manager
   Tel: +86-24-86728299
   Fax: +86-24-86728298
   E-Mail: qiuxiao1971@163.com

3. Submission Correspondent

   Ms. Diana Hong
   Mr. Lee Fu
   Shanghai Mid-Link Business Consulting Co., Ltd
   Suite 8D, Zhongshan Zhongxin Mansion
   No.19, Lane 999, Zhongshan No.2 Road(S)
   Shanghai, 200030, China

4. Device Name and Classification:

   Device Trade Name: HG Oxygen Concentrator
   Modes: HG5-W & HG5-WN
   Device Common Name: Oxygen Concentrator
   Device Classification Name: generator, oxygen, portable

Review Panel: Anesthesiology
Product Code: CAW
Regulation Number:868.5440
Device Class: II

5. Predicate Device Identification:
   Delphi Portable Oxygen Concentrator
   K-number: K073242

6. Intended Use:

   HG Oxygen concentrator is intended to provide supplemental oxygen to patient continuously in home, hospital or health care facility environments. It is not for supporting or sustaining life.

7. Device Description:

   The subject device, HG Oxygen Concentrator, contains two models, HG5-W and HG5-WN. These two models follow the same design principle, same raw material, same main function and same specification. The only difference between the two models is that HG5-WN oxygen concentrator provide an addition interface on the front panel, which can be connected to the nebulizer and supply air to the nebulizer.

   The subject device, HG Oxygen Concentrator, is intend to provide ≥90% supplemental low flow oxygen, which is separated from the room air, to the patient in the home, nursing homes, patient care facilities, etc. Oxygen is delivered to the patient via a nasal cannula or oxygen mask, but these accessories are not supplied with the concentrator, the user shall select appropriate and legally marketed accessories themselves. The subject device is not intended to support or sustain life.

   The subject device, HG Oxygen Concentrator, uses Pressure Swing Adsorption technology to deliver concentrated oxygen. Two chambers and a valve allow compressed air to enter the embedded sieve, which will separate the nitrogen from the air. When one chamber is receiving compressed air, the other is expelling nitrogen back to the air. The cycle is repeated continuously. The concentrated oxygen created at each cycle is stored in an oxygen store cylinder to be delivered to a patient. This working principle is widely used in the oxygen concentrator, it will not arise new question of safety and effectiveness.

8. Test Conclusion

   Laboratory testing was conducted to validate and verify that HG Oxygen Concentrator met all design specifications and was substantially equivalent to the predicate device.

9. Substantially Equivalent Conclusion:
   The subject device, HG Oxygen Concentrator, is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Shenyang Canta Medical TECH Company, Limited
C/O Ms. Diana Hong
General Manager
Shanghai Mid-Link Business Consulting Company, Limited
Suite 8D, Zhongshan Zhongxin Masion
No.19, Lane 999, Zhongshan No.2 Road(S)
Shanghai, 200030
CHINA

AUG 2 7 2008

Re: K081508
Trade/Device Name: HG Oxygen Concentrator
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: May 27, 2008
Received: May 29, 2008

Dear Ms. Hong:

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

Indication for Use

510(k) Number:

Device Name: HG Oxygen Concentrator

Indications for Use:

HG Oxygen concentrator is intended to provide supplemental oxygen to patient continuously in home, hospital or health care facility environments. It is not for supporting or sustaining life.

Prescription Use __√__ 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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K081508