SEP 2 3 2008 K081267

SUMMARY OF SAFETY AND EFFECTIVENESS

"510(k) SUMMARY"
Prepared by: YC Lee
Date Prepared: April 14, 2007

9.1	Manufacturer:	KEDL International Limited Unit C, Lot 1718-DD221, Tan Cheung, Sai Kung, New Territories, Hong Kong
9.2	Submitted By:	Contact – P/L Biomedical Lee Leichter 7690 Cameron Circle Fort Myers, FL 33912 Tel – 239-768-1118 Fax – 815-550-0162
9.3	Trade/Proprietary Name:	Hygeia-5 Oxygen Concentrator
9.4	Common/Usual Name:	Oxygen Concentrator
9.5	Classification Name:	Portable Oxygen Generator Panel: 73 Procode: CAW

9.6 Comparison to Currently Marketed Devices
The Hygeia-5 Oxygen concentrators are substantially equivalent to the Devilbiss 5 Liter Oxygen concentrators (K991722) and Sequal Integra Model 6323 concentrators (K942082).

9.7 Device Description
The Hygeia-5 Oxygen Concentrators are prescription devices designed to provide an inexpensive supply of supplemental oxygen in a home or institution without a continuous source of purified oxygen. They are not life-supporting or life-sustaining devices. The device operates on the same pressure swing adsorption (PSA) principle as other oxygen concentrators. They use the same type of molecular sieve material that binds with the water and nitrogen in filtered room air to leave a gas that is approximately 93% oxygen when delivered to the patient. Most concentrators use two sieve beds, alternating between the beds using one bed to generate the oxygen while the other is flushed for regeneration. The Hygeia-5 differs in as much as it has 5 smaller beds instead of two large beds and uses a rotating valve to distribute the air to the sieve beds and control the cycle of the adsorption and regeneration. This concept/design is similar to the Sequal device. As with other concentrators, it has an Oxygen reservoir to collect the oxygen before

distribution to the patient. The Oxygen concentrator is also equipped with electronic alarms to monitor for power failure and over or under pressure of the pneumatic system.

9.8 Indication/Intended Use

The Hygeia-5 Oxygen concentrators are indicated to provide supplemental oxygen for adults requiring supplemental oxygen and are intended to be used in the home or institutional environment. The device is not intended for life support nor does it provide any patient monitoring capabilities.

9.9 Technological Characteristics

The technological characteristics are the same as the predicate devices.

9.10 Performance Data

Verification testing has confirmed the product meets its specifications.

9.11 Conclusion

KEDL International concludes based on the information presented that the Hygeia-5 Concentrators are substantially equivalent to products currently legally marketed in the USA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 3 2008

KEDL International Limited
C/O Mr. Lee Leichter
P/L Biomedical
7690 Cameron Circle
Fort Myers, FL 33912

Re: K081267
Trade/Device Name: Hygeia-5 Oxygen Concentrator
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: September 22, 2008
Received: September 22, 2008

Dear Mr. Leichter:

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

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) File Number: K081267

Device Name: Hygeia-5 Oxygen Concentrator

Indications For Use: The Hygeia-5 Oxygen concentrators are indicated to provide supplemental oxygen for adults requiring supplemental oxygen and are intended to be used in the home or institutional environment. The device is not intended for life support nor does it provide any patient monitoring capabilities.

Prescription Use ✓ AND/OR Over-The-Counter Use ____

(Per 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: K081267