K080391

510(K) SUMMARY
(as required by 807.92(c))

MAR 18 2008

Submitter of 510(k):

Medical Depot
99 Seaview Blvd
Port Washington, NY 11050
USA

Phone: 877-224-0946
Fax: 516-998-4601

Contact Person: Randy Rosen

Date of Summary: January 23, 2008

Trade/Proprietary Name: Drive Solstice Oxygen Concentrator

Classification Name: Generator, Oxygen, Portable

Product Code: CAW

Intended Use:

The intended function and use of the Drive Solistice Oxygen Concentrator (models 18050 and 18055) is to provide supplemental oxygen to patients with respiratory disorders, by separating nitrogen from room air, by way of a molecular sieve. It is not intended to sustain or support life.

Device Description:

The Drive Solstice Oxygen Concentrator is a PSA (Pressure Swing Adsorption) system Oxygen Concentrator, the output of oxygen is 1 to 5 liter per minute. Room air enters the piston type compressor via a series of filters for removing dust particles. The output compressed air is directed by a pneumatic valve into one of the two sieve beds which is full of the adsorption material -molecular sieve. Nitrogen is adsorbed by the molecular sieve as the pressure increases; oxygen flows through the molecular sieve and concentrates at the sieve bed top. The enriched oxygen is divided into two streams; one stream enters a storage tank. The pressurized oxygen is regulated down to the suitable pressure, an adjustable flow meter and out to the patient. At the same time the second bed is in exhausted status, the molecular sieve desorbs nitrogen as the pressure decreases; another oxygen stream from first bed enters the top of the second bed, promotes purging the nitrogen and is exhausted into the atmosphere. Two sieve beds exchange the role of oxygen concentration and continue to produce 90% oxygen to the patient.

Predicate Device:

Invacare Platinum 5 Oxygen Concentrator - K020386 – Invacare Corporation
A&J-POCA01 Oxygen Concentrator – K071608 – Zhongshan A&J Medical Equipment Co., Ltd

Substantial Equivalence:

Medical Depot claims the proposed device to be substantially equivalent to the device previously cleared by FDA in K071608. Medical Depot claims this equivalence because the proposed device has an equivalent intended use, manufacturing materials, operating principles, and physical, operational specification as compared to the predicate device. The Medical Depot Concentrator is identical to this predicate device except for the labels

The similarities and differences between the proposed and predicate devices have been identified and explained in the Comparison Matrix which has been included in Section 9 of this submission. Additionally, this matrix is included as an attachment to the 510(k) summary. These differences have no effect on safety and effectiveness.

Ver. 2.6.06

mfg.	Invacare	Drive	Zhongshan A&J Medical
product name	Invacare Platinum XL 5-Liter O2 Concentrator with Sens O2	Solstice	A&J-POCA01 Oxygen Concentrator
model No.	IRC5LXO2	18050, 18055	POCA01
concentration levels	95.6% to 87% at all flow rates	1-5 LPM: 90% ± 3%)	1-5 LPM: 90% ± 3%)
delivery rate	0.5 to 5 LPM	1 to 5 LPM	1 to 5 LPM
Outlet pressure	5 psi +/- 0.5 psi	8.5 psig	8.5 psig
alarms	battery-free power loss; sieve performance; oxygen monitor; low-flow; compressor 35 psi pressure-releif valve	pressure relief / thermal protection on compressor high / low pressure power failure low oxygen purity(optional) current overload shoutdown	pressure relief / thermal protection on compressor high / low pressure power failure low oxygen purity(optional) current overload shoutdown
electrical rating	115V 60Hz	115V/60Hz	115V/60Hz
power consumption	4.3 amps average @ 5L/min. (400W)	300W average	300W average
battery			
filters	Cabinet, outlet HEPA, compressor inlet	Cabinet, intake,outlet HEPA filter	Cabinet, intake,outlet HEPA filter
dimensions (in. L x W x H)	14-3/8 x 18-3/8 x 26-3/8	12x14x20	12x14x20
weight (lbs)	51	38	38
specs/ standards			
approvals		Class II equip double insulated Type B Applied Part	Class II equip double insulated Type B Applied Part
operating system	pressure based system	Timed cycle / pressure swing	Timed cycle / pressure swing
sound level	50dBA avg	45~48dBA	45~48dBA
operating environment		50 to 95 deg. F, Humidity: 30% to 75%	50 to 95 deg. F, Humidity: 30% to 75%
warranty	5 yrs		
valve	unique designed (? Popet style valve	The dual solenoid, three-position, five-way valve increases shift efficiency, valve life, and reliability and comes with a lifetime warranty	The dual solenoid, three-position, five-way valve increases shift efficiency, valve life, and reliability and comes with a lifetime warranty
compressor	Thomas Based Double wobble, may be chineese made today	GSE-280A compressor	GSE-280A compressor
other	self-diagnostic electronics compatible w/HomeFill II O2 filling system		
Oxygen Sensor	Yes (Optional)	Yes (Optional)	Yes (Optional)
HEPA Filter	Yes	Yes	Yes
ASTM 1464	Meets Standard	Meets Standard	Meets Standard

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 18 2008

Medical Depot
C/O Mr. Daniel W. Lehtonen
Responsible Third Party Official
Intertek Testing Services NA, Incorporated
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

Re: K080391
Trade/Device Name: Drive Solistice Oxygen Concentrator
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: March 3, 2008
Received: March 4, 2008

Dear Mr. Lehtonen:

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

Indications for Use

510(k) Number (if known): _____

Device Name: Drive Solistice Oxygen Concentrator

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

510(k) Number: K090391

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)