510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990, 21 CFR 807.87, 21 CFR 807.92, Format for Traditional and Abbreviated 510(k)s.

1. Name of Submitter, Contact Person and Date Summary Prepared:

Applicant:	SWR International, Ltd Room 2706 27th Floor, South Tower Guangzhou World Trade Center Complex 37 Huanshi Road East, Guangzhou China
Contact:	Ms. J. Deng
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Date of Preparation:	November 24, 2009

2. Device Trade Name and Common Name:

Trade Name:	AXS-590Hi and AXS-590i
Common/Usual Name:	Portable oxygen generator
Classification Name:	generator, oxygen, portable
Regulation Number:	21 CFR 868.5440

3. Product Code: CAW

Device Class: Class 2

4. Predicate Device: Invacare Platinum 510(k) K020386

5. Description of the Device:

The AXS-590Hi and AXS-590i oxygen concentrators are 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.

Both the SWR AXS-590Hi and AXS-590i oxygen concentrators and the predicate Invacare Platinum oxygen concentrators are of the pressure-swing-adsorber (PSA) variety. In PSA type oxygen concentrator devices, the molecular sieve material operates as a catalyst that binds with the water and nitrogen in filtered room air to leave a gas that is typically not less than 85% oxygen when delivered to the patient. Air is exposed, at a certain pressure, to molecular sieve material that selectively retains nitrogen and other components until they are subsequently released when the pressure is reduced, thus the term pressure-swing. The compressor creates a vacuum to suck room air through a pre-filter into a holding tank. At the same time, downstream of the compressor, the air from the previous cycle is pressurized into one of the two aluminum molecular sieve tanks. As the oxygen is forced out of the end of the tank, it enters a "T" fitting that directs most of the gas to flush the nitrogen out of the second molecular sieve tank into the ambient air. The remaining oxygen is delivered to the patient. On the next cycle, the air is directed into the second molecular sieve tank with the oxygen generated flushing the first tank and continuing the supply to the patient. This repetitive cycle generates the oxygen necessary to flush and prepare the saturated sieve tank while supplying the patient with a continuous flow of high concentration oxygen. Also see section 11.1 of this submission.

6. Intended Use of the Device:

The intended function and use of the SWR International AXS-590Hi and AXS-590i oxygen concentrators 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.

7. Comparison of technological characteristics with Predicate Device:
The AXS-590Hi and AXS-590i oxygen concentrators perform the same function as the Invacare Platinum oxygen concentrator and performs this function by the same methodology (molecular sieve).

8. Discussion of Non-clinical Studies:
The AXS-590Hi and AXS-590i oxygen concentrators have had extensive bench testing performed. This testing was designed to insure compliance with the standards identified in sections 9 and 18 of this submission. The testing was also performed to show that the devices meet the requirements specifications and that hazard mitigations are effective.

9. Conclusion:
The AXS-590Hi and AXS-590i oxygen concentrators are as safe and effective as the predicate device and provide an inexpensive supply of supplemental oxygen in a home or institution without a continuous source of purified oxygen.

SWR International Ltd.
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

NOV 2 4 2009

SWR International, Limited
C/O Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, L.L.C.
1394 25th Street Northwest
Buffalo, Minnesota 55313

Re: K091650
Trade/Device Name: AXS-590Hi and AXS-590i Oxygen Concentrators
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: November 11, 2009
Received: November 12, 2009

Dear Mr. Job:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 Indications for Use

510(k) Number (if known): K091650

Device Name: AXS-590Hi and AXS-590i Oxygen Concentrators

The intended function and use of the SWR International AXS-590Hi and AXS-590i oxygen concentrators 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.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schultz

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

510(k) Number: K091650

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