Section 14 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR 807.92.

The assigned 510(k) number is: K032818

SUBMITTER INFORMATION

Submitter:	Inogen, Inc. 120 Cremona Drive, Suite B Goleta, CA 93117
Contact:	John Wells Director of Operations
Telephone: **Fax:**	805-562-0500 805-961-1409
Date Prepared:	9 September 2003

DEVICE NAME AND CLASSIFICATION

Proprietary Name:	Inogen One Oxygen Concentrator
Common Name:	Oxygen Concentrator
Product Code:	CAW
Medical Specialty:	Anesthesiology
Device Classification:	Class 2
Regulation Number:	21 CFR section 868.5440

PREDICATE DEVICE INFORMATION

Substantial equivalence of the Inogen One Oxygen Concentrator is claimed to the following legally marketed predicate devices:

- AirSep Corporation, Life Style Oxygen Concentrator, 510(k) # K020324

DEVICE DESCRIPTION

The Inogen One Oxygen Concentrator is used on a prescriptive basis by patients requiring supplemental oxygen. Patients may include but are not restricted to those with chronic obstructive pulmonary disease (COPD). The device is not intended to be life sustaining or to be life supporting. It is used with a nasal cannula to channel oxygen from the device to the patient. The concentrator and the nasal cannula are non-sterile.

The Inogen One Oxygen Concentrator provides approximately 90% oxygen to the patient on a demand flow basis at an "equivalent" rate of 1.0 liters per minute to 5.0 liters to minute in increments of 0.5 liters per minute.

The Inogen One Oxygen Concentrator is capable of continuous use in a home, institution, vehicles and various mobile environments. Power options include 110 – 220 VAC, 12 – 14 VDC or rechargeable batteries.

The Inogen One Oxygen Concentrator uses molecular sieve / pressure swing adsorption technology. Ambient air is drawn thru particle filters by a compressor and forced thru molecular sieve beds, which adsorb nitrogen and allow oxygen to pass. The airflow is then changed and nitrogen is desorbed from the molecular sieve, allowing it to adsorb again during the next cycle. Oxygen is collected in an accumulator reservoir. Waste nitrogen is exhausted back into the room. A series of sieve beds, a manifold with precision valves, sensors and embedded software to control the cycle are used to make the system function.

Oxygen is delivered to the patient on a demand flow basis in precise amounts during the inhalation part of the breathing cycle. This conserver technology eliminates waste of unused oxygen at other times in the breathing cycle when it is not needed. Inogen One Oxygen Concentrator senses the beginning of the inhalation cycle and releases a specified dose of oxygen enriched gas from the accumulator reservoir, thru a final filter, into the connected nasal cannula and onto the patient.

The design of the Inogen One Oxygen Concentrator has focused on maximizing subsystem efficiencies and miniaturizing components to enable continuous duty use and to provide minimal weight and battery operation for mobile use.

The basic technology of the Inogen One Oxygen Concentrator is equivalent to other approved oxygen concentrators. The principles of operation are equivalent to the predicate device noted in the submission.

INDICATIONS for USE

The Inogen One Oxygen Concentrator is used on a prescriptive basis by patients requiring supplemental oxygen. It supplies a high concentration of oxygen and is used with a nasal cannula to channel oxygen from the concentrator to the patient. The Inogen One Oxygen Concentrator may be used in a home, institution, vehicles and various mobile environments.

TECHNOLOGICAL CHARACTERISTICS

The Inogen One Oxygen Concentrator utilizes well established technologies. Molecular sieve / pressure swing adsorption technology has been used for many years to produce oxygen. Demand flow delivery systems have been in use on portable oxygen sources for many years. The capability of AC, DC or rechargeable battery power has also been in use.

Technologies utilized by the Inogen One Oxygen Concentrator brings forth no new questions of safety and effectiveness. These technologies are also currently being used in the identified predicate device.

Benchtop performance testing has demonstrated that the Inogen One Oxygen Concentrator is equivalent to the AirSep LifeStyle Oxygen Concentrator.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 3 2004

Mr. John Wells
Director of Operations
Inogen, Incorporated
120 Cremona Drive, Suite B
Goleta, CA 93117

Re: K032818
Trade Name: Inogen One Oxygen Concentrator
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: April 2, 2004
Received: April 5, 2004

Dear Mr. Wells:

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.

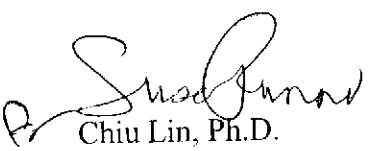
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4646. 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/dsma/dsmamain.html.

Sincerely yours,



Chiu Lin, Ph.D.
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Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

001207

Indications for Use

510(k) Number (if known): K032818

Device Name: Inogen One Oxygen Concentrator

Indications for Use:

The Inogen One Oxygen Concentrator is used on a prescriptive basis by patients requiring supplemental oxygen. It supplies a high concentration of oxygen and is used with a nasal cannula to channel oxygen from the concentrator to the patient. The Inogen One Oxygen Concentrator may be used in a home, institution, vehicles and various mobile environments.

Prescription Use: X **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(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)

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

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