K132489

JUN 20 2014

5. 510(k) Summary

510(k) Owner/ Submitter:	Inogen, Inc. 326 Bollay Drive Goleta, California 93117 P: (805) 562-0500 F: (805) 562-0516
Contact Person:	Mara Korsunsky Inogen, Inc. Director, Quality, Regulatory, and Compliance P: (805) 562-0629 F: (805) 562-0516 E: mkorsunsky@inogen.net
Date Prepared:	August 5, 2013
Trade Name:	Inogen At Home Oxygen Concentrator (AKA Inogen At Home/ Model GS-100)
Device Type: (Common Name)	Oxygen Concentrator
Classification Name:	Portable Oxygen Generator
Classification Regulation:	868.5440
Class:	II
Panel:	Anesthesiology
Product Code:	CAW
Predicate Device(s):	Respironics, Inc., Respironics L4 Oxygen Concentrator (EverFlo), K061261 Inogen, Inc., Inogen One Oxygen Concentrator, K032818

Device Description:

The Inogen At Home is a stationary concentrator providing approximately 90% oxygen to patients on a continuous flow basis at a rate of 1.0 liter per minute (LPM) to 5.0 liters per minute (LPM), in 1.0 liter per minute (LPM) increments. Nasal cannula channels oxygen from device to patient; both concentrator

and nasal cannula are non-sterile. The device is capable of continuous use in the home or in an institutional setting.

The Inogen At Home can be powered by mains AC power found in the home or in an institutional setting. The Inogen At Home includes a detachable AC power cord to make the electrical connection to the AC mains.

The Inogen At Home utilizes Pressure Swing Adsorption (PSA) technology to produce oxygen. Oxygen is separated from ambient air under pressure by molecular characteristics and affinity for adsorbent material. The molecular sieve preferentially adsorbs nitrogen, allowing enriched oxygen to collect in an accumulator; the process then swings to low pressure to desorb the nitrogen, exhausting it back into the environment. A series of sieve beds, manifold with precision valves, sensors, and embedded software are used collectively to govern system functionality.

Intended Use/ Indications for Use:

The Inogen At Home 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 At Home Oxygen Concentrator may be used in a home or institution.

Technological Characteristics:

The Inogen At Home has a similar indications statement and technological characteristics (materials, design, and energy source) as the predicate devices. It raises neither new nor different questions of safety and effectiveness compared to the predicate devices; it is substantially equivalent.

Non-clinical Performance Data:

The Inogen At Home conforms with EN ISO 8359:2012, Oxygen Concentrators for Medical Use – Safety Requirements (ISO 8359:1996, Second edition, Amendment 1), ASTM F 1464:2005, Oxygen Concentrators for Domiciliary Use, IEC 60601-1, Medical Electrical Equipment -- Part 1: General requirements for safety, 1988; Amendment1, 1991-11, Amendment2, 1995.

Biocompatability testing included the evaluation of particulate matter, Ozone, Volatile Organic Compounds, Carbon Dioxide, and Carbon Monoxide. Performance testing included the assessment of electrical safety/ compatability, software functionality, fire mitigation, vibration and noise, temperature and altitude ranges, outlet pressure, flow indicator accuracy, and oxygen concentration.

This supports a determination of substantial equivalence.

Conclusion:
The Inogen At Home is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 20, 2014

Inogen, Inc.
Mara Korsunsky
Director, Quality, Regulatory, and Compliance
326 Bollay Drive
Goleta, California 93117

Re: K132489
Trade/Device Name: Inogen At Home Oxygen Concentrator
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable oxygen generator
Regulatory Class: II
Product Code: CAW
Dated: May 21, 2014
Received: May 22, 2014

Dear Ms. Korsunsky:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact 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. 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132489

Device Name: Inogen At Home Oxygen Concentrator

Indications for Use:

The Inogen At Home 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 At Home Oxygen Concentrator may be used in a home or institution.

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 IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Anya C. Harry -S
2014.06.19
13:43:53 -04'00'

Page 1 of