LifeChoice by InovaLabs

K113317

DEC 2 8 2011

Special 510(k) Summary (reference 510(k) #K072688)

Non-confidential Summary of Safety and Effectiveness

Submitter Information:

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Contact:

H. David Shockley
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Date: Submitted: November, 2011

Device Classification Name: Generator, Oxygen, Portable
Product Code: CAW
Classification: Class II
Regulation No.: 21 CFR 868.5440
Panel: Anesthesiology
Specific Device Name: LifeChoice Oxygen Concentrator
Model: OXY1000

Description of the Device: The LifeChoice Oxygen Concentrator is a prescription use device for patients needing supplemental high concentration oxygen. The LifeChoice is not intended to be life sustaining or to be life supporting. The device provides approximately 90% oxygen to patients on a demand flow basis at an equivalent rate of 1.0 liter per minute to 5.0 liters per minute in increments of 1.0 liter per minute.

The LifeChoice is a portable device which can be used in a home, institution or travel environment. The device uses molecular sieve pressure swing adsorption technology. This is a proven technology to concentrate room air into high concentration oxygen.

Indications for Use: The LifeChoice Oxygen Concentrator is used on a prescriptive basis by patients who are diagnosed as requiring supplemental oxygen. This oxygen concentrator will provide supplemental, high concentration oxygen to these patients. It is not life supporting nor life sustaining. It may be used continuously in a home, institution or travel environment. The LifeChoice is also portable.

Technological Characteristics: The LifeChoice Oxygen Concentrator utilizes well established technologies. Molecular sieve pressure swing adsorption technology has been used for many years to produce high concentration oxygen. Also, demand flow delivery systems have been in use on portable oxygen devices for many years. The capability to power the device with AC, DC and/or rechargeable batteries has also been in use for many years.

The technologies used in the modifications to the LifeChoice Oxygen Concentrator do not create any new questions of safety and effectiveness. Benchtop performance testing and comparison of performance characteristics have demonstrated that the modified LifeChoice is substantially equivalent to the previously marketed version.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mr. H. David Shockley
Vice President
Inova Labs, Incorporated
3500 Comsouth Drive, Suite 100
Austin, Texas 78744

DEC 2 8 2011

Re: K113317
Trade/Device Name: LifeChoice Concentrator, Model OXY 1000
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: December 16, 2011
Received: December 20, 2011

Dear Mr. Shockley:

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 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

Anthony D. Watson, B.S., M.S., M.B.A.
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): ___K113317_____

Device Name: Inova Labs LifeChoice Oxygen Concentrator

Indications for Use:

The LifeChoice Oxygen Concentrator is used on a prescriptive basis by patients who are diagnosed as requiring supplemental oxygen. This oxygen concentrator will provide supplemental, high concentration oxygen to these patients. It is not life supporting nor life sustaining. It may be used continuously in a home, institution or travel environment. The LifeChoice is also portable.

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

510(k) Number: K113317