

MALLINCKRODT

510(k) Summary

Puritan-Bennett Aeris 590 Oxygen Concentrator

Submitter Information

Submitter: Puritan-Bennett Corporation
(a subsidiary of Mallinckrodt Inc.)
3 Missouri Research Park Drive
St. Charles, MO 63304.

Contact: Tony Keaveney
Regulatory Affairs Manager
Tel: (314) 498 3365
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Preparation Date: 13 September 1999

Device Name

Proprietary Name: Aeris 590 with OCI
Common Name: Oxygen concentrator
Classification Name: Portable oxygen generator (73 CAW) as per 21 CFR 868.5440

Predicate Device Equivalence

Puritan-Bennett is claiming substantial equivalence to the Puritan-Bennett Companion 590 oxygen concentrator with OCI (Oxygen Concentration Indicator), K895141.

Device Description

An oxygen concentrator takes in room air, filters it and separates the nitrogen from the air under pressure, allowing only oxygen and trace gases to pass through to the oxygen outlet connection to the patient while exhausting a nitrogen-rich air mixture back into the room. The principle components of the Aeris 590 oxygen concentrator include a compressor, two molecular sieve containers, a valve system and a printed circuit board. The

compressor draws in room air, pressurizes it and forces it through the pneumatic circuit of the device. As the air passes through one sieve container, the nitrogen bonds with the molecular sieve material within the pressurized container and allows only the oxygen and trace gases to flow out of the container. This oxygen rich mixture (+90% oxygen) is then delivered to the patient at a regulated pressure and flowrate. The valve system regulates the airflow through the sieve containers alternately. While one is pressurized and producing oxygen, the other is being depressurized and exhausting the nitrogen in preparation for the next cycle. A programmable logic device on the printed circuit board controls the timing of this cycling process. The OCI (Oxygen Concentration Indicator) provides an indication of the oxygen concentration of the output gas and includes alarm features.

Intended Use

The Aeris 590 oxygen concentrator with OCI is intended to provide supplemental oxygen to patients who may have difficulty extracting oxygen from the air that they breathe. The patient would normally receive the oxygen mixture via a nasal cannula. The device delivers over 90% oxygen at flow rates ranging from 0 to 5 liters per minute. It is primarily intended to be used in the patient's homes but may also be used in nursing homes or sub-acute care environments. It is not intended as life sustaining or life supporting device. The device has no contraindications.

Comparison of Technological Characteristics

The Aeris 590 with OCI will continue to use the same enclosure, the same compressor assembly, the same methods of gas filtration, the same method of pressure regulation and the same molecular sieve material as the Companion 590 device. It will continue to have the same audible and visual alarms as the unmodified device and the same set of accessories are also specified. Both devices are capable of supplying oxygen at flow rates of 0 to 5 L/min.

The intended use of the device remains unchanged as does its risk classification. The modified device will continue to be indicated for use for both pediatric and adult patients and will continue to be a prescription only device. Both devices are intended only as sources of supplemental oxygen and are not intended to be life supporting devices. Neither device have any contraindications.

The valve system in the Companion 590 is a pneumatic valve system controlled by low voltage solenoids. In the Aeris 590, the valve system has changed to a directly actuated valve system. The reservoir tank has been removed from the pneumatic circuit of the Aeris 590 and the sieve canister assembly has been made easier to assembly.

The oxygen concentration performance of the Companion 590 has been improved in the Aeris 590. It has an improved tolerance in the 1 to 4 L/min range and performs better at 5 L/min.

Summary of Performance Testing

The Aeris 590 with OCI successfully passed tests in the following areas;

- Electrical Safety
- Electromagnetic Compatibility (EMC)
- Mechanical/Climatic
- Software
- Device Performance

Conclusions

In summary, Puritan-Bennett has demonstrated that the Aeris 590 oxygen concentrator is safe and effective. The combined testing and analysis of results provides assurance that the device meets its specifications and is safe and effective for its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 8 1999

Mr. Tony Keaveney
Puritan-Bennett Corporation
2200 Faraday Avenue
St. Charles, MO 63304

Re: K993088
Aeris 590 with OCI
Regulatory Class: II (two)
Product Code: 73 CAW
Dated: September 13, 1999
Received: September 16, 1999

Dear Mr. Keaveney:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

Device name: Aeris 590 Oxygen Concentrator with OCI

Indications for Use: The Puritan-Bennett Aeris 590 oxygen concentrator with OCI is intended to provide supplemental oxygen to patients who may have difficulty extracting oxygen from the air that they breathe. It is intended to be used with both pediatric and adult patients. It is not intended as life sustaining or life supporting device. The device has no contraindications.

Prescription Use: Yes

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: Yes *or* Over-The-Counter Use: _____

Premarket Notification 510(k) Number: _____

VK 993048

M. Payne

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number _____