

OCT 22 1999



510(k) Summary

Puritan-Bennett Helios Portable Liquid Oxygen System

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
Fax: (314) 939 5535

Preparation Date: 24 September 1999

Device Name

Proprietary Name: Helios Portable Liquid Oxygen System
Common Name: Portable Liquid Oxygen Unit
Classification Name: Portable Liquid Oxygen Unit (73 BYJ) as per 21 CFR 868.5655

Predicate Device Equivalence

Puritan-Bennett is claiming substantial equivalence to the Puritan-Bennett Companion 550 Liquid Oxygen (Lox) System, K933930.

Device Description

The Helios portable liquid oxygen system consists of a vacuum insulated cryogenic container and plumbing that includes pressure relief valves, heat exchanger tubes and a pneumatic conserving device. The vacuum insulated container allows oxygen to be stored in its liquid state under pressure where the system pressure is controlled by the relief valve. When the patient opens the flow control valve, the liquid oxygen is withdrawn from the container into a vaporizing coil. Once in the vaporizing coil, ambient heat is absorbed by the liquid oxygen, converting it into a gas and warming it to near room temperature. The gas finally passes through the flow control valve and on to the patient at the prescribed metered rate. The device is intended to be used in conjunction with a larger liquid oxygen reservoir where it is filled by mating it to the fill connection on the top of the larger system. The Helios device is a purely mechanical device and contains no electrical or electronic components.

Intended Use

The Helios portable lox system is intended to provide supplemental oxygen to oxygen therapy patients who may have difficulty extracting oxygen from the air that they breathe. The patient would normally receive the oxygen via a nasal cannula. The device delivers 100% oxygen at 12 different flow settings. It is intended to be used as an ambulatory source of oxygen both inside and outside the patient's home. It is not intended as life sustaining or life supporting device. The device has no contraindications.

Comparison of Technological Characteristics

The intended use of the modified device remains unchanged as does its risk classification. The modified device will continue to be indicated for use for the same 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 has any contraindications.

Both the modified and unmodified device include a vacuum insulated cryogenic container and plumbing that includes pressure relief valves, heat exchanger tubes and a pneumatic conserving device. The cryogenic container in the Helios device is smaller than that in the Companion device and the design of the associated valve and heat exchanger assemblies have been optimized. The enclosure has also been changed to accommodate the change in physical dimensions of the modified device. The conservation ratio of the pneumatic conserver has been changed from 2:1 to 4:1 to allow the device to last longer between filling. The Helios device can be used in the horizontal position whereas the Companion device may only be used in the vertical position.

Summary of Performance Testing

The Helios liquid oxygen system successfully passed tests in the following areas;

- Mechanical/Climatic
- Device Performance

Conclusions

In summary, Puritan-Bennett has demonstrated that the Helios portable liquid oxygen system 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.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 22 1999

Mr. Tony Keaveney
Puritan-Bennett Corporation
3 Missouri Research Park Drive
St. Charles, MO 63304

Re: K993220
Helios Portable Liquid Oxygen System •
Regulatory Class: II (two)
Product Code: 73 BYJ
Dated: September 24, 1999
Received: September 27, 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.

Page 2 - Mr. Tony Keaveney

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,



Wolf Sapirstein, M.D.

Acting 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: Helios Portable Liquid Oxygen System

Indications for Use: The Puritan-Bennett Helios Portable Liquid Oxygen System is intended to provide supplemental oxygen to oxygen therapy patients who may have difficulty extracting oxygen from the air that they breathe. It is intended to be used as an ambulatory source of oxygen both inside and outside the patient's home. 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:

or

Over-The-Counter Use:

Premarket Notification 510(k) Number:

K993220

[Signature]
(Division Sign-Off)

Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number

K993220