

OCT 28 1998

**Spiracle Technology  
Bi-Flow D/R  
510(k) SUMMARY**

**Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared**

**Submitter**

Guy Gansel  
Spiracle Technology  
16520 Harbor Blvd., #D  
Fountain Valley, CA 92708-1360  
Telephone: (714) 418-1091  
Facsimile: (714) 418-1095

**Contact Person**

Guy Gansel  
Spiracle Technology  
16520 Harbor Blvd., #D  
Fountain Valley, CA 92708-1360  
Telephone: (714) 418-1091  
Facsimile: (714) 418-1095

**Name of Device**

Trade Name: Bi-Flow Demand/Resuscitator (Bi-Flow D/R)  
Common Name: Demand Valve  
Classification Name: Powered Emergency Ventilator  
Device Classification: 21 CFR § 868.5925

**Predicate Devices**

Allied Healthcare Products (Life Support Products) Models:

063 Demand Valve  
063R Demand Valve

**Intended Use**

The Bi-Flow D/R is designed to provide manual mechanical ventilation triggered by the operator to a nonbreathing patient. This is accomplished by providing the patient a source of oxygen from the Bi-Flow D/R through a device such as a facemask or endotracheal tube. Between the oxygen source and the patient interface is the Bi-Flow valve, which allows for the release of oxygen from its source when triggered by the operator. For the spontaneous breathing patient, the Bi-Flow D/R may be used as an Inhalator. This is accomplished by the patient triggering the valve with his/her negative inspiratory force and the source gas being delivered to the patient through a face mask.

**Technological Characteristics and Substantial Equivalence**

The Bi-Flow D/R is designed to provide manual mechanical ventilation triggered by the operator to a nonbreathing patient. The small portable device is primarily constructed of aluminum components and utilizes a plastic and silicone rubber inhalation/exhalation valve. The device is gas powered and has no electronic components or software. The device is pilot actuated.

The Bi-Flow D/R is substantially equivalent to other demand valves including the Allied Healthcare Products (Life Support Products) CPR/Demand Valve Model 063 and CPR/Demand Valve Model 063R. These predicate devices, like the Bi-Flow D/R are pneumatically powered devices used to provide emergency respiratory support. These predicate device was sold prior to 1976.

## **Performance Data**

Extensive functional testing of the Bi-Flow D/R has been performed. In addition, testing of the device has been performed under various environmental conditions, including impact/drop testing, vomitus testing, immersion testing, storage temperature testing and operating temperature testing. The functional and environmental testing performed on the device demonstrated that the device meets its performance objectives and complies with applicable standards and FDA guidelines.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT 28 1998

Mr. Guy Gansel  
Spiracle Technology  
16520 Harbor Boulevard, #D  
Fountain Valley, CA 92708-1360

Re: K982225  
Bi-Flow Demand/Resuscitator Model 504  
Regulatory Class: II (two)  
Product Code: 73 BTL  
Dated: September 30, 1998  
Received: October 1, 1998

Dear Mr. Gansel:

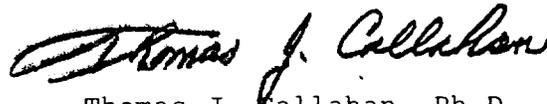
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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 (Premarket 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.

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

**Spiracle Technology  
Bi-Flow D/R  
Indication For Use Statement**

510(k) Reference Number:

K982225

Statement of Indications for Use:

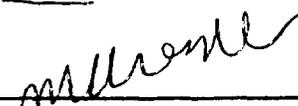
The Bi-Flow D/R is designed to provide manual mechanical ventilation triggered by the operator to a nonbreathing patient. This is accomplished by providing the patient a source of oxygen from the Bi-Flow D/R through a device such as a facemask or endotracheal tube. Between the oxygen source and the patient interface is the Bi-Flow valve, which allows for the release of oxygen from its source when triggered by the operator thus providing emergency respiratory support. For the spontaneous breathing patient, the Bi-Flow D/R may be used as an Inhalator. This is accomplished by the patient triggering the valve with his/her negative inspiratory force and the source gas being delivered to the patient through a face mask.

Additionally, there is a non-rebreathing valve (reusable version or single patient use version) attached to the Bi-Flow D/R which directs the patient's exhalation back to atmosphere. The combination of the Bi-Flow D/R and the non-rebreathing valve as a single device is commonly referred to as a Demand Valve.

The power for the device is provided by the compressed oxygen source. There is no additional source of power for this device.

The Bi-Flow D/R will be sold by Spiracle Technology only by or on the order of a physician and is intended to be used exclusively by trained health care professionals. The Bi-Flow D/R will be sold as a component of a respiratory support system to be configured by the health care provider. As such, it will be compatible with all commonly available oxygen source and face mask connections.

Prescription Use

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number \_\_\_\_\_