K031718

3 510(K) SUMMARY [AS REQUIRED BY 21 CFR 807.92(C)]

Submitter's Name / Contact Person

Manufacturer
Horizon Medical Products, Inc.
One Horizon Way
Manchester, Georgia 31816

Contact
Scott Moeller
Director of Quality Assurance and Regulatory Affairs

General Information

Trade Name	LifeValve Central Venous Catheter		
Common Name	Central venous catheter		
Classification Name	Percutaneous, implanted, long-term intravascular catheter Classification Number: 21 CFR §880.5970 Classification Panel: General Hospital Product Code: LJS		
Equivalent Device	**Product**	**Manufacturer**	**510(k) #**
	Single Lumen Valved Catheter	Strato Medical Corp	K924851

Device Description

The LifeValve Central Venous Catheter includes a catheter and introduction components. The catheter is a percutaneous central venous catheter that incorporates a bidirectional valve assembly at the distal tip. The catheter is comprised of radiopaque silicone tubing, a molded radiopaque silicone tip with radiopaque marker band and a polyester implant cuff. It utilizes a luer lock connector and catheter Snap-Lock™ for proximal fittings. The catheter is equipped with a stylet stiffener. Each product is packaged in a sterile tray with 8 French introducer components. The family of LifeValve products includes externally communicating central venous catheters in two overall lengths, 50 and 65 cm.

Intended Use

The LifeValve Central Venous Catheter is indicated for patient therapy requiring acute or long-term (chronic) central venous access for the infusion of medications, parenteral solutions, parenteral nutrition solutions, or blood products, and for the withdrawal of blood samples.

Substantial Equivalence Comparison

The LifeValve Central Venous Catheter and the predicate Strato Medical Single Lumen Valved Catheter are identical in intended use and fundamental scientific technology. The two devices are substantially similar in configuration, dimensions, and materials. Minor configurational, dimensional, and material changes have improved device performance. The design changes were evaluated through risk analysis and qualified through design verification testing and biomaterial safety evaluations following established Design Control procedures. The changes raise no new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 2003

Mr. Scott Moeller
Director, Quality Assurance & Regulatory Affairs
Horizon /medical Products, Incorporated
1 Horizon Way
Manchester, Georgia 31816

Re: K031718
Trade/Device Name: LieValve Central Venous Catheter
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: June 2, 2003
Received: June 4, 2003

Dear Mr. Moeller:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim 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 STATEMENT

510(k) Number (if known): K031718

Device Name: LifeValve Central Venous Catheter

Indications for Use:

The LifeValve Central Venous Catheter is indicated for patient therapy requiring acute or long-term (chronic) central venous access for the infusion of medications, parenteral solutions, parenteral nutrition solutions, or blood products, and for the withdrawal of blood samples.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cucarte

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K031718