K050176

510(k) Summary [as required by 21 CFR 807.92(c)]

FEB 25 2005

Submitter's Name / Contact Person

Manufacturer
RITA Medical Systems, Inc.
One Horizon Way
Manchester, Georgia 31816

Contact
Mary Gossard, M.S.
Manager, Regulatory Affairs

General Information

Trade Name	Vortex® EZ Port Access System
Common Name	Vascular access port
Classification Name	Subcutaneous, implanted, intravascular infusion port and catheter Classification Number: 21 CFR §880.5965 Classification Panel: General Hospital Product Code: 80 LJT (a Class II device)
Modified Devices	LifePort® VTX® Access System (K010767) LifePort® LPS 7013 (K905852)

Device Description

The Vortex® EZ Port Access System is a device comprised of a vascular access port, a catheter, locking mechanism and introduction components. The Vortex® EZ Port is available in a Delrin port body configuration with a self sealing silicone septum designed to maintain integrity after repeated punctures with a non-coring needle. The port base is crafted of silicone so that the port can be sutured to the underlying tissue anywhere around this base. A pre-attached or a detached/attachable catheter is offered in either polyurethane or silicone models with or without a highly radiopaque tip molded on. The products are packaged in sterile trays with introduction components.

Intended Use / Indications

The Vortex® EZ Port Access System is indicated for any patient requiring repeated access of the vascular system or other selected body site, for the delivery of medications, nutritional supplementation, fluids, blood, blood products, and sampling of blood.

Substantial Equivalence Comparison

The Vortex® EZ Port Access System and the modified devices, LifePort® VTX® Access System and the LPS 7013 model of the LifePort® ports with silicone and polyurethane catheters share identical intended uses and fundamental scientific technology. The subject and modified devices are substantially similar in configuration, dimensions, and materials. The Vortex® EZ Port Access System design was evaluated through risk analysis and qualified through design verification testing following established Design Control procedures. No new questions of safety or effectiveness were raised for the Vortex® EZ Port Access System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 25 2005

Ms. Mary Gossard
Manager, Regulatory Affairs
RITA Medical Systems
One Horizon Way
Manchester, Georgia 31816

Re: K050176
Trade/Device Name: Vortex® EZ Port Access System
Regulation Number: 880.5965
Regulation Name: Subcutaneous, Implanted Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT
Dated: January 25, 2005
Received: January 26, 2005

Dear Ms. Gossard:

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 (240) 276-0115. 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/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
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): K050176

Device Name: **Vortex® EZ Port Access System**

Indications for Use:

The Vortex® EZ Port Access System is indicated for any patient requiring repeated access of the vascular system or other selected body site, for the delivery of medications, nutritional supplementation, fluids, blood, blood products, and sampling of blood.

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)

[signature]

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

(510(k) Number: K050176