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5.0 510(k) Summary

Manufacturer and sponsor of the 510(k)

RITA Medical Systems, Inc.
One Horizon Way
Manchester, Georgia 31816
800-472-5221 Phone
706-846-5226 fax
Establishment registration number: 1056436

FEB - 1 2007

Device Identification:

Proprietary Name:	Vortex® CT Port Access System
Common Name:	Vascular access port
Classification Name:	Subcutaneous, implanted, intravascular infusion port & catheter
Classification Number:	21 CFR §880.5965
Classification Panel:	General Hospital
Product Code:	LJT
Regulatory Class:	II
Proprietary Name:	LifeGuard® Safety Infusion Set
Common Name:	Port Access Infusion set
Classification Name:	Set, administration, intravascular
Classification Number:	21 CFR §880.5440
Classification Panel:	General Hospital
Product Code:	FPA
Regulatory Class:	II

Legally marketed device to which equivalence is claimed:

C.R. Bard PowerPort 510(k) K060812

Primary contact for correspondence
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Device Description

The legally marketed devices that form the basis for this 510(k) submission is Horizon Medical Products' Vortex® Access System (K010767 cleared April 10, 2001), and the LifeGuard safety infusion set K013871 cleared March 6, 2002).

The Vortex® CT Port is a Titanium port with a self sealing silicone rubber septum designed to maintain integrity after punctures with a non-coring needle. The port has a hollow area, or reservoir, under the septum through which fluid passes during infusion or aspiration.

The Vortex design features a proprietary reservoir with rounded walls giving it a toroidal shape. The outlet stem is located tangential to the reservoir wall allows fluid to pass between the reservoir and the catheter.

The Vortex® Port Access systems offer models with single lumen 7.5 French to 9.6 French catheters made from either polyurethane or silicone. The catheters all contain radiopacifiers, and depth markings.

A more detailed description of the components of the Vortex® Port Access System is as follows;

Port Body: The body of the port is crafted of Titanium. Suture sites are incorporated into the port base to facilitate anchoring to the underlying tissue.

Reservoir: The reservoir is the hollow area under the septum, into which the non-coring needle is inserted for administration or withdrawal of fluids. The toroidal wall shape and a tangential outlet stem interface to facilitate flushing of the system.

Outlet stem: The port outlet stem is made from Titanium. Connection to the stem is accomplished through barbed connectors. The stem is located tangentially to the reservoir. The catheter is placed over stem, and locked into place. This creates a fluid connection with the reservoir.

Port septum: The port septum is the component through which the non-coring needle is inserted. The septum is self sealing, designed to maintain integrity after repeated punctures and is constructed from silicone (NuSil MED 4850).

Catheter: The available catheters are 7.5 or 9.6 French made from silicone (NuSil MED 4765) impregnated with a 15% $BaSO_4$ in the cannula. The catheters include a blue stripe and tip loaded 25% $BaSO_4$ for improved radiopacity. All catheters have depth markings to 65 cm to allow for precise placement.

Locking Mechanism: The cylindrical locking mechanism is made from silicone. The lock is advanced over the catheter until it positively locks onto the port stem, thereby compressing the catheter onto the stem and sealing the system.

Implantation: The Vortex® Port Access System is totally implanted in the body. The catheter is placed by percutaneous puncture technique with the distal tip at the juncture of the superior vena cava and right atrium via the jugular or subclavian vein. A subcutaneous pocket is prepared for placement of the port. The appropriate catheter length is determined, and the excess is trimmed by cutting straight across the proximal end. The catheter is marked up to 65 cm to allow more precise placement in the desired location. The catheter is attached to the port using the locking mechanism. The port body is secured by suturing through the base to the underlying fascia prior to wound closure.

The Vortex® port has significant physical and performance characteristics that make it an ideal candidate for indication for power injection. These characteristics include; All Titanium construction for maximum strength, barbed outlet stems for ease and simplicity of catheter connection, and maximum connection strength, combination locking mechanism / strain relief for simple locking, and maximum catheter protection.

The LifeGuard safety infusion set is a port access needle set with an integrated proprietary safety feature to prevent re-bound injury. The safety infusion set includes a huber needle, a winged housing, non-DEHP PVC extension legs, and a luer standard connector.

It has come to RITA's attention that ports have and are being used for power injection studies. RITA currently makes no claims, and provides no instructions for this procedure. The purpose of this 510(k), and the studies which have been conducted, is to establish a safe and effective way to conduct a power injection study through ports which are deemed to be appropriate for this type of use.

When used for power injection, the port is accessed, using qualified infusion sets, in the standard fashion, per the standard instructions. The supplemental instructions will then be followed for power injection. Power injection involves the use of a power syringe to inject contrast media in order to complete a study.

Intended Use / Indications

The Vortex® CT Port Access System is indicated for any adult 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.

The Vortex® CT ports can accommodate a 5 ml/sec injection rate of contrast dye. This should only be attempted using a 20 gauge or 19 gauge non-Y site LifeGuard® infusion set model #'s LG-19-XXX, and LG-20-XXX.

Summary of the technological characteristics of your device compared to the predicate device

The following table summarizes the technological comparison between the Vortex® CT and Bard PowerPort:

Technological Characteristic	RITA Vortex® CT	C.R. Bard PowerPort (K060812)
Intended use, power injection	Accommodates a 5 ml/sec injection rate of contrast dye. This should only be attempted using a 20 gauge or larger non-Y site LifeGuard® CT infusion set.	Accommodates a 5 ml/sec injection rate of contrast dye injected at up to 300 psi without damaging the port or catheter.
Design	Port system with attachable catheter.	Port system with attachable catheter.
Material	Titanium Grade 2	Titanium
Shape	Round port system with tangential outlet	Triangular port system with central outlet
Included labeling	Instructions for use (General) Instructions for use power injection Vortex® CT poster for CT offices Patient information booklet Patient ID card with key fob Patient chart labeling Product label	Educational booklet for patients, nurses, placers, and CT department Wall charts for CT department and placers Discharge kits for patients (includes Patient ID card with key fob and bracelet)
Needles used for Access	LifeGuard non-Y site safety infusion sets in 19 or 20 Ga	LifiLock non-Y site safety infusion sets in 19 or 20 Ga

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Summary of the non-clinical performance data

The following non-clinical tests were performed as the basis for establishing substantial equivalence to the predicate device, as well as safety and effectiveness of the indication for use:

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Test Description	Sample Size	Test Description	Required Results
Sterilization exposure	All	The samples shall be exposed to a 2x EtO sterilization cycle.	All samples must be capable of withstanding a 2X sterilization cycle
Physiological exposure	All	Maintain samples in a 0.9% saline bath at 37°C for 24hrs prior to testing and between any tests. During the initial 24 hour preconditioning, the samples shall be flushed and locked with a Vancomycin solution (1g/1000cc of normal saline).	All samples must be capable of withstanding physiological conditioning
Power injection Performance Test	18	Inject 200 ml of an 11.8 cP solution through the port at 5ml/sec. Evaluate system for leaks and damage	Maximum Pressure: $(U-\bar{X})/s \geq k$ where k = 1.96 for an AQL level of 0.65 Catheter material failure: no bursts, leaks, / plastic deformations allowed
Simulated Power Injection	30	Inject 150 ml of an 11.8 cP solution through the port at 5ml/sec with 19 Ga and 20 Ga needles. Evaluate system for leaks and damage	All samples must meet expected flow rate and pressure withstand requirements
Dynamic Failure Test	18	Inject 200 an 11.8 cP solution through the port at increasing flow rates until failure occurs.	Data shall be gathered to support label claims and determine the operational safety factor.
Static Burst Test	18	Inject 100ml of a saline solution through the port with the catheter occluded. Record the maximum pressure	Data shall be gathered to support label claims.
Life Cycle Power Injection Test	10	Inject 200 ml of an 11.8 cP solution through the port at 5ml/sec. Evaluate system for leaks and damage. Repeat the test 9 times	Catheter material failure: no bursts, leaks, / plastic deformations allowed
Cyclic testing	30, 10 cycles per port	Inject 150 ml of an 11.8 cP solution through the port at 5ml/sec with 19 Ga needles. Repeat cycle 10 times. Evaluate system for leaks and damage.	All samples must withstand 10 cycles without leaking or bursting. The expected maximum number of power injection cycles is 5.
Port Patency Verification	5	Withdraw simulated blood through port needle combination to determine flow rate of fully patent system.	Blood return must be easily and empirically verifiable to establish safety of power injection
Port Occlusion Test	10	Inject 100ml of a saline solution through the port with the catheter occluded. Record the maximum pressure	Data shall be gathered to support label claims.
Puncture Life	2	To test the durability of the septum with needles expected to be used in power injection.	Establish label claim for largest needle likely to be used during power injection

Summary of the clinical performance data

No clinical tests were performed to determine substantial equivalence.

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Conclusions drawn from the non-clinical performance data

The non-clinical tests demonstrate that the device is as safe, as effective for the modified intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. David Smith
Director, of Vascular Products Engineering
RITA Medical Systems, Incorporated
One Horizon Way
Manchester, Georgia 31816

FEB - 1 2007

Re: K062414
Trade/Device Name: Vortex® CT Port Access Systems and LifeGuard® Safety Infusion Set
Regulation Number: 880.5965
Regulation Name: Subcutaneous, Implanted Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT, FPA
Dated: January 24, 2007
Received: January 25, 2007

Dear Mr. Smith:

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.

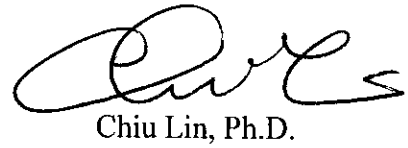
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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

The LifeGuard® Safety Administration Set intended use has been reproduced below in the FDA's required format.

Indications for Use

510(k) Number (if known): K062414

Device Name: LifeGuard® Safety Infusion Set

Indications for Use:

The LifeGuard® Safety Infusion Set is an administration set with a non-coring right angle needle and manually activated needle-stick prevention safety mechanism. The device is used to access surgically implanted vascular ports.

The LifeGuard® Safety Infusion Set is indicated for use in the administration of fluids and drugs, as well as blood sampling through surgically implanted vascular ports.

When used with the Vortex® CT Port Access System, the LifeGuard® Safety Infusion Set is also indicated for power injection of contrast media into the central venous system. For power injection of contrast media, only models LG-19-75, LG-19-100, LG-20-75, LG-20-100, and LG-20-150 may be used at a maximum infusion rate of 5ml/sec.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anthony D. Watson

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4.0 Indications for Use Statement

The Vortex® CT Port Access System intended use has been reproduced below in the FDA's required format.

Indications for Use

510(k) Number (if known): K062414

Device Name: Vortex® CT Port Access System

Indications for Use:

The Vortex® CT 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 the sampling of blood.
When used with non Y site LifeGuard Safety infusion sets in 20 Ga or 19Ga sizes, the Vortex® CT Port Access System is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/sec.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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