



Food and Drug Administration
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May 21, 2015

Cook Incorporated
Mr. Steven Lawrie
Regulatory Affairs Team Lead
750 Daniels Way, P.O. Box 489
Bloomington, IN 47402

Re: K150733

Trade/Device Name: Vital-Port[®] Vascular Access System Power Injectable Port
Regulation Number: 21 CFR 880.5965
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT
Dated: April 23, 2015
Received: April 24, 2015

Dear Mr. Lawrie:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 Tina
Kiang -S

for Erin I. Keith, M.S.

Director

Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K150733

Device Name

Vital-Port® Vascular Access System Power Injectable Port

Indications for Use (Describe)

The Vital-Port® Vascular Access System Power Injectable Port is intended for use for patient therapy requiring repeated vascular access for infusion therapy, power injected diagnostic techniques using contrast media, and blood infusion/withdrawal. For the power injection of contrast media, the maximum recommended infusion rate is 5 ml/s using media with a maximum viscosity of 11.8 cP.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

K150733

Submitted By: Steven Lawrie
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Phone: (812) 335-3575 x104518
Fax: (812) 332-0281
Date Prepared: 11 May 2015

Device:

Trade Name: Vital-Port[®] Vascular Access System Power Injectable Port
Common Name: Port & Catheter, Implanted, Subcutaneous, Intravascular
Classification Name: Subcutaneous, implanted, intravascular infusion port and catheter
LJT (21 CFR §880.5965)
Class/Panel: Class II, General Hospital

Indications for Use:

The Vital-Port Vascular Access System Power Injectable Port is intended for use for patient therapy requiring repeated vascular access for infusion therapy, power injected diagnostic techniques using contrast media, and blood infusion/withdrawal. For the power injection of contrast media, the maximum recommended infusion rate is 5 ml/s using media with a maximum viscosity of 11.8 cP.

Predicate Device:

The subject device in this submission is substantially equivalent to the predicate device, the Vital-Port Vascular Access System Power Injectable Port, cleared on September 30, 2008 under 510(k) number K081425.

Technological Characteristics and Comparison to Predicate Device:

It has been demonstrated that the proposed Vital-Port Vascular Access System Power Injectable Port is substantially equivalent to the predicate device, the Vital-Port Vascular Access System Power Injectable Port (K081425), in that these devices are identical in terms of intended use, principals of operation, materials of construction, and basic technological characteristics. The performance and reliability of the subject device are supported by testing. A full comparison of the predicate and subject devices is presented in Table 1.



Table 1: Comparison Table for the Vital-Port Vascular Access System Power Injectable Port

	PREDICATE DEVICE	SUBJECT DEVICE
	Vital-Port Vascular Access System Power Injectable Port (K081425)	Vital-Port Vascular Access System Power Injectable Port (Subject of this Submission)
Regulation Number	880.5965	Identical
Product Code	LJT	Identical
Classification	Class II	Identical
Intended Use	For use in patient therapy requiring repeated vascular access for infusion therapy, power injected diagnostic techniques using contrast media and blood infusion/withdrawal. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s with a maximum viscosity of 11.8 cP.	Identical
Port Body Material	Titanium	Identical
Catheter	9.5 Fr Silicone 9.5 Fr Polyurethane	7.5 Fr Silicone
Catheter Lock	Polysulfone	Identical
Catheter Lock Reinforcing Sleeve	Silicone	Identical
Septum	Silicone	Identical
Suture Hole Plug	Silicone	Identical
Sterilization	EtO	Identical
Sterility Assurance Level (SAL)	10 ⁻⁶	Identical
Packaging	Inner and Outer Tray with Tyvek® Lidstock	Identical

Device Description:

The Vital-Port Vascular Access System Power Injectable Port is a titanium body vascular access port with a silicone septum and silicone filled suture holes. The subject device’s catheter is a 7.5 Fr silicone catheter that may be supplied pre-attached or detached. The catheter lock is polysulfone with a silicone strain relief. The supplied catheter is 50 cm in length.

When used with a power injectable infusion set, the Vital-Port Vascular Access System Power Injectable Port device is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s using contrast with a maximum viscosity of 11.8 cP. The maximum pressure limit setting for power injectors used with the Vital-Port may not exceed 325 psi and the flow rate may not exceed 5 ml/s.



Table 2: Device Specifications

Subject Device	Catheter size and material	Maximum Flow Rate*	Injection Pressure Limit Setting
The Vital-Port Vascular Access System Power Injectable Port	7.5 Fr silicone	5 ml/s	325 psi

*Flow rates were achieved using a room temperature infusate equivalent to Omnipaque 300[®] and a Medrad Injector. Omnipaque 300 has a viscosity of 11.8 centipoise at room temperature (20 °C). A change in the temperature or viscosity of the media will result in a change in achievable flow rate. Omnipaque 300 is a registered trademark of GE Healthcare.

Test Data:

A risk assessment was performed to assess the risks presented by the subject device. Design control activities were then performed in order to address the modifications noted in Table 1. Specifically, the following tests have been conducted on the subject device to ensure reliable design and performance under the specified design requirements, and no new risks were identified for the subject device with respect to the predicate device. These tests include:

- **Dynamic Failure Flow Test** - The purpose of this testing was to subject the port system to increasing flow rates to determine the maximum sustainable flow rate. The acceptance criterion was a minimum of 5 ml/s without a failure. The acceptance criterion for the testing was met.
- **Instantaneous Burst Test** - The purpose of this testing was to determine the ultimate pressure limit of the Vital-Port system. The acceptance criterion was a mean burst pressure greater than the mean reservoir pressures characterized in previous testing. The acceptance criterion for the testing was met.
- **Static Burst Test** - The purpose of this testing was to determine the effects, if any, of elevated pressures over a defined period of time. All devices were required to withstand 120 psi (827.3 KPa) for three minutes without failure. All test articles met or exceeded the acceptance criterion.
- **Cyclic/Puncture Life Test** - The acceptance criterion was no leakage at a flow rate of 5 ml/s. All test articles met this criterion.
- **Life Cycle Power Injection Test** - The purpose of this test was to verify the Vital-Port would maintain system integrity after multiple power injections. Each Vital-Port configuration maintained system integrity during all consecutive power injections. The acceptance criterion for the testing was met.

In conclusion, the results of these tests support a determination of substantial equivalence to the predicate device.