K081425

SEP 30 2008

510(k) Summary

Submitted by:

Jim Ferguson
Quality Systems Manager
Cook Vascular, Incorporated
1186 Montgomery Lane
Vandergrift, Pa 15690
724-845-8621, XT 2227
April 10, 2006

Device:

Trade name:	**Cook Vascular, Inc. Vital-Port Vascular Access System Power Injectable Port**
Proposed Classification:	**Subcutaneous, implanted, intravascular infusion port and catheter, 880.5965**

Predicate Devices:

The Cook Vascular, Inc. Vital-Port Vascular Access System Power Injectable Port Set is similar in terms of intended use, and exactly the same as materials of construction and technology characteristics to the predicate devices that have been found substantially equivalent.

Device Description:

The proposed device is exactly the same as the predicate devices.

Substantial Equivalence:

This device will be manufactured to specified process controls and a Quality Assurance program. This device will undergo packaging exactly the same as the devices currently manufactured by Cook Vascular. This device will undergo sterilization exactly the same as the devices currently marketed and distributed. Being the same as the predicate devices in respect to indication for use, materials and physical construction, this device meets the requirements for section 510(k) substantial equivalence. It is to be noted that this device has not changed in design, materials and/or methods.

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

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

Test Data:

The **Cook Vascular, Inc. Vital-Port Vascular Access System Power Injectable Port** was subjected to the flowing tests to assure reliable design and performance under the specified testing parameters. These tests were comprised of:

1. Dynamic Failure Flow Test
2. Instantaneous Burst Test
3. Static Burst Test
4. Puncture Life Test
5. Cyclic Test
6. Life Cycle Power Injection Test

The results of these tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its use as a Vital-Port Vascular Access System Power Injectable Port.

Based on empirical evidence, Cook Vascular, Inc. recommends for power injection of 9000 series models of Vital-Ports® with a maximum limit of 5mL/sec and 325psi. We reasonably assume that our testing provides "worst-case" scenarios for contrast media viscosity, catheter length and septum access. Our tested catheter length is greater than 70cm, while we assume the implanted length to be within a 20cm – 50cm range. Furthermore, our tested contrast media viscosity was at 11.8cP, while suggested usage for vendor supplied contrast media calls for pre-heating of the media prior to injection, this pre-heating could reduce viscosity by nearly half as some heated viscous contrast media could be as low as 4.9cP. Applying these expected clinical parameters would reduce overall system pressure and thereby increase the operational safety factor. Lastly, sufficient warnings against over pressurization of the silicone catheter systems are highly recommended as empirical evidence suggests that a catheter could fail prior to the injection machine depressurizing the system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 3 0 2008

Mr. Jim Ferguson
Quality System Manager
Cook Vascular, Incorporated
1186 Montgomery Lane
Vandergrift, Pennsylvania 15690

Re: K081425
Trade/Device Name: Cook Vascular, Inc. 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: September 19, 2008
Received: September 22, 2008

Dear Mr. Ferguson:

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.

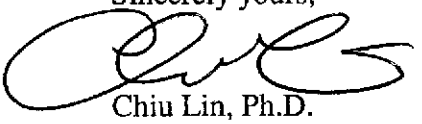
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 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): **K081425**

Device Name: **Cook Vascular Inc. Vital-Port Vascular Access System Power Injectable Port**

Indications For Use:

The devices are for use in 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/sec using media with a maximum viscosity of 11.8 cP.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

For Chmielewski

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

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