K082481

5. 510(k) Summary

Sponsor: VasoNova Inc.
1368 Bordeaux Drive
Sunnyvale, CA 94089

DEC 17 2008

Contact Person: Tina Cheng
Phone Number: 510.589.6084
Fax Number: 650 644.2456
Prepared: August 27, 2008

Trade Name: VasoNova FlowPICC Catheter, name subject to change
Common Name: Percutaneous, implanted, long-term intravascular catheter
Classification: II
Product Code: LJS 21 CFR 880.5970
Advisory Panel: General and Plastic Surgery

Predicate Device: Bard PowerPICC Catheter
Cook Turbo-Ject Catheter

Device Description
The FlowPICC Catheter is a double lumen open-ended PICC designed for power injection through one designated lumen. The FlowPICC Catheter is fabricated from a soft, radiopaque, biocompatible polyurethane material with a working length of 50 cm with markings in 5 cm increments. The catheter is packaged with accessories necessary for implantation of a PICC catheter using a Seldinger or modified Seldinger technique. A stylet and adaptor sideport are provided to assist in catheter insertion.

Intended Use
The FlowPICC catheter is indicated for short or long-term access to the central venous system for intravenous therapy, power injection of contrast media and blood sampling.

Performance Data
In vitro and *in vivo* testing demonstrates that the VasoNova FlowPICC Catheter meets all acceptance criteria.

Substantial Equivalence
The VasoNova FlowPICC catheter has the same intended use, technological characteristics and principles of operation as its predicate devices. Performance data demonstrate that the VasoNova FlowPICC is as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 2008

Ms. Tina Cheng
Director, Product Development
Vasonova, Incorporated
1368 Bordeaux Drive, Suite 100
Sunnyvale, California 94089

Re: K082481
Trade/Device Name: VasoNova FlowPICC Catheter
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: December 5, 2008
Received: December 8, 2008

Dear Ms. Cheng:

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 S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Indications for Use

510(k) Number (if known): **K082481**

Device Name: **VasoNova FlowPICC Catheter**

Indications for use:

The FlowPICC Catheter is indicated for short or long-term peripheral access to the central venous system for intravenous therapy and injection of contrast media. For blood sampling, infusions, or therapies, use a 5F or larger catheter. The maximum recommended infusion rate is 5cc/sec.

The FlowPICC Catheter is indicated for use by itself or with the FlowPICC System (Stylet and Console) sold separately.

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

510(k) Number: K082481