Vacora® 14G Probe Improvements
510(k) Summary of Safety and Effectiveness
21 CFR 807.92.

K082621

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a summary of the safety and effectiveness information upon which substantial equivalence determination is based as follows:

1. Submitter Information:

Applicant: Bard Peripheral Vascular, Inc
1625 West 3rd Street
P.O. Box 1740
Tempe, Arizona 85280

Phone: 480-379-2836

Fax: 480-449-2546

Contact: Cindy Moss

2. Subject Device Name:

Device Trade Name: Vacora® Vacuum Assisted Biopsy System

Common or Usual Name: Instrument, Biopsy

Classification: Class II

Classification Panel: Gastroenterology/Urology

3. Predicate Device:

Bard® Vacora® Vacuum Assisted Biopsy System (K0062832, clearance date October 20, 2006)

4. Summary of Change:

The modification from the predicate to the subject Vacora® Vacuum Assisted Biopsy System include design improvements to the driver, probe and coaxial; packaging configuration changes, a change in method of sterilization for sterile accessories, and added performance characteristics.

5. Device Description:

The Vacora® Biopsy System is a self-contained, electro-mechanical medical device used to collect breast tissue samples for diagnostic analysis of breast abnormalities. The system is comprised of the non-sterile reusable driver module, and biopsy needle probes, coaxial cannulae/cannula sets and various accessories needed to accomplish a breast tissue biopsy. Most of the accessories are sterile, single use, disposable components of the system.

6. Intended Use of Device:

The Vacora® Biopsy System is intended for diagnostic sampling of breast tissue during a biopsy procedure.

7. Technological Comparison to Predicate Device:

The technological characteristics of the subject device are identical to those of the predicate device in terms of intended use, indications for use, fundamental scientific technology, operating principle, user population, and sterilization level.

8. Conclusions:

The modified Vacora® Biopsy System met all predetermined acceptance criteria of the design verification and validation testing performed under design controls, and are substantially equivalent to the unmodified, currently marketed Vacora® Biopsy System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 5 2008

C.R. Bard, Inc.
% Ms. Cindy Moss
Associate Project Manager,
Regulatory Affairs
1625 West 3rd Street
P.O. Box 1740
Tempe, Arizona 85280-1740

Re: K082681
Trade/Device Name: Vacora® Vacuum Assisted Biopsy System
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: KNW
Dated: September 12, 2008
Received: September 15, 2008

Dear Ms. Moss:

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,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K082681

Device Name: Vacora® Vacuum Assisted Biopsy System

Indications For Use: The Vacora® Biopsy System is indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. The instrument is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality.

The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality (e.g., malignancy). When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

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)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082681