FINESSE™ Ultra Breast Biopsy System

510(k) Summary of Safety and Effectiveness
21 CFR 807.92

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:

Submitter Information:

Applicant: Bard Peripheral Vascular, Inc
1415 West 3rd Street
P.O. Box 1740
Tempe, Arizona 85281

Phone: 480-379-2836

Fax: 480-449-2546

Contact: Cindy Moss, Project Manager, Regulatory Affairs

Date September 8, 2009

Subject Device Name:

Device Trade Name:	**FINESSE™ Ultra Breast Biopsy System**
Common or Usual Name:	Biopsy Instrument (21 CFR 876.1075, Product Code KNW)
Classification:	Class II
Classification Panel:	Gastroenterology/Urology

Predicate Devices:

- Vacora® Vacuum Assisted Breast Biopsy System (K082681, cleared October 15, 2008), manufactured by Bard Peripheral Vascular, Inc (hereafter referred to as Vacora).

- Mammotome® Hand Held 8G Probe (K003297, cleared January 18, 2001), manufactured by Ethicon Endo-Surgery, Inc. (hereafter referred to as Mammotome).

- Vacuum Assisted Spring Loaded Core Biopsy Device (K034021, cleared September 8, 2004), manufactured by Suros Surgical Systems (hereafter referred to as Celero™ Vacuum Assisted Core Biopsy Device or Celero)

Device Description:

The subject device, the FINESSE™ Ultra Breast Biopsy System, is a handheld, self-contained, vacuum assisted breast biopsy system for use with ultrasound imaging guidance. The system is comprised of (1) a reusable hand piece (driver) that contains all electronics and components to generate a vacuum without the need to be connected to any external power supply or vacuum source and (2) a disposable biopsy probe capable of excising and storing multiple tissue samples without the need for the probe to be removed from the patient between samples.

Intended Use of Device:

The FINESSE™ Ultra Breast Biopsy System is intended to obtain soft tissue samples for diagnostic and histological analysis of breast abnormalities.

Indications for Use of Device:

The FINESSE™ Ultra Breast Biopsy System is indicated to obtain tissue samples from the breast or axillary lymph nodes for diagnostic analysis 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.

Technological Comparison to Predicate Devices:

The FINESSE™ Ultra Breast Biopsy System has the following similarities to the predicate devices:

- Similar intended use
- Similar indications for use
- Same target population
- Similar fundamental scientific technology
- Similar operating principle
- Similar packaging materials
- Same sterility assurance level and method of sterilization

Conclusions:

The FINESSE™ Ultra Breast Biopsy System met all acceptance criteria for design verification and validation, as specified by applicable standards, guidance, test protocols and/or customer inputs. The FINESSE™ Ultra Breast Biopsy System is substantially equivalent to the legally marketed predicate devices, the Vacora, Mammotome, and the Celero.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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C.R. Bard, Inc.
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Mr. Robert Mosenkis
President
5200 Butler Pike
Plymouth Meeting, Pennsylvania 19462-1298

Re: K093068
Trade/Device Name: FINESSE™ Ultra Breast Biopsy System
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: KNW
Dated: October 23, 2009
Received: October 27, 2009

Dear Mr. Mosenkis:

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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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/cdrh/mdr/ 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K093068

Device Name: FINESSE™ Ultra Breast Biopsy System

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Prescription Use X AND/OR Over-The-Counter Use_____ (Part21 CFR 801 Subpart D) (21CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093068

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