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K972328

Appendix II

Summary of Safety and Effectiveness

The PBB, a disposable breast biopsy device, is substantially equivalent to like devices in commercial distribution. These similar devices are marketed by United States Surgical Corporation (USSC), C.R. Bard, and Biopsys Medical.

PBB, USSC, C.R. Bard and Biopsys devices are all used to obtain biopsies within breast tissue. These devices are used in conjunction with instrument accessories which are used to mount the devices on a stereotactic table. These devices are all used with stereotactic mammographic imaging systems.

The PBB device is like the C.R. Bard and Biopsys devices in that they all remove a localized biopsy. These devices obturate up to the lesion, leaving intact the tissue in route to the target area.

The PBB Instrument Accessories (Instrument Holder, Needle Holder, and Stop) are similar to the instrument holding devices marketed by USSC, Biopsys, and C.R. Bard Magnum devices in that they are all reusable devices. All of these devices are used to mount their biopsy instrument on stereotactic tables.

The PBB and similar devices on the market have components that are of similar materials that are well known and extensively used by device manufacturers. Materials which have patient contact consist of surgical stainless steel and thermoplastics. Biocompatibility testing will be conducted on sterile component samples, according to ISO-10993 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing. The testing will include, but is not limited to Cytotoxicity, Sensitization, and Irritation/Intracutaneous Reactivity. This device is categorized as Body Contact - Tissue/Bone/Dentin Communicating for a limited duration (≤ 24 hours).

The PBB device is available with and without electrosurgery capability. The PBB device with electrosurgery capability and the USSC ABBI device both have monopolar electrosurgical capability. Both are equipped with a 4mm male plug to allow their use with standard monopolar electrosurgical generators. The PBB device with Electrosurgery capability complies with the applicable safety, performance, and labeling requirements of the American National Standard Institute and Association for the Advancement of Medical Instrumentation, ANSI/AAMI ES1-1993 Safe current limits for electromedical apparatus and ANSI/AAMI HF18-1993 Electrosurgical devices.

The method of sterilization and the method used to validate the sterilization process are in compliance with the ANSI/AAMI/ISO 11135-1994 Medical Devices - Validation and routine control of ethylene oxide sterilization.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 7 1998

Ms. Julie Powell
Quality Assurance and Regulatory Affairs Director
Imaging Surgical
Division of Imaging Medical Technologies
8850 M89 Box 351
Richland, Michigan 49083-03513

Re: K972328
Trade Name: Percutaneous Breast Biopsy (PBB) and Percutaneous Breast Biopsy (PBB) Instrument Accessories
Regulatory Class: II
Product Code: KNW
Dated: April 1, 1998
Received: April 2, 1998

Dear Ms. Powell:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to 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). You may, therefore, market these devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your devices in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your devices, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K972328

Device Name: Percutaneous Breast Biopsy (PBB) and Percutaneous Breast Biopsy (PBB) Instrument Accessories

Indications for Use:

Diagnostic device used to obtain localized biopsies within breast tissue. Device is for diagnostics purpose only, it is not for therapeutic use. To be used with Percutaneous Breast Biopsy Instrument Accessories (Instrument Holder, Needle Holder, and Stop), which are attached to a stereotactic table and used in conjunction with stereotactic mammographic imaging systems.

(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 General Restorative Devices
510(k) Number K972328

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)