DEC 27 1999

K99 3936

Appendix II

Summary of Safety and Effectiveness

The SiteSelect device, a disposable breast biopsy device, is substantially equivalent to like devices in commercial distribution. These devices are marketed by Imagyn Surgical and United States Surgical Corporation (USSC).

SiteSelect, Imagyn Surgical, and USSC 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 used with stereotactic mammographic imaging systems.

The construction, materials, sterilization, and method of operation of the SiteSelect devices are identical to the Imagyn Surgical SiteSelect devices currently on the market.

The major difference between SiteSelect and USSC ABBI devices is that the ABBI device removes tissue in route to and including the target area. The SiteSelect device obturates up to the lesion, leaving intact the tissue in route to the target area.

Standards/guidelines used for the testing and manufacturing of the SiteSelect device are:

ANSI/AAMI/ISO 11135-1994 Medical Devices - Validation and routine control of ethylene oxide sterilization ANSI/AAMI/ISO 11135-1994 Medical Devices - Validation and routine control of ethylene oxide sterilization

ISO 10993-7: 1995 EtO Sterilization Residuals; for Limited Exposure Devices

FDA's Proposed Residue Limits; FDA, 43FR 279.82 (June 23, 1978)

ISO-10993 Biological evaluation of Medical Devices Part 1: Evaluation and Testing

EN 1441 Risk Analysis

ISO 11607 Packaging for Sterilized Devices

Appendix II

Summary of Safety and Effectiveness (continued)

Clinical Summary:

Data from a multi-center, non-randomized study was collected. Eighty-seven patients, from 3 sites, underwent SiteSelect stereotactic breast biopsy procedures to evaluate device for the use in the removal of mammographically detected abnormalities for diagnostic evaluation.

Twelve patients (14%) were diagnosed with malignant lesions. Of the 12 patients with malignant lesions 2 (16.7%) had negative margins, 7 (58.3%) had margin involvement, and 3 (25%) were undetermined. Consistent with standard of care for excisional biopsies, all patients with malignancies were treated with a surgical procedure after diagnostic SiteSelect procedure.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 27 1999

Ms. Julie Powell
Quality Assurance/Regulatory Affairs Director
Imagyn Surgical
8850 M89, Box 351
Richland, Michigan 49083-0351

Re: K993936
Trade Name: SiteSelect Breast Biopsy Device
Regulatory Class: II
Product Code: KNW
Dated: November 18, 1999
Received: November 19, 1999

Dear Ms. Powell:

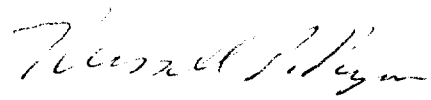
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 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 (Premarket Approval), 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 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 device 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 device as described in your 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 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 device, 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): K993936

Device Name: SiteSelect Breast Biopsy Device

Indications for Use:

SiteSelect is a disposable, single use, diagnostic device used to obtain localized large core biopsies of breast tissue of a mammographic abnormality, identified by the placement of a needle/ localization wire, which is suspect to be malignant. The SiteSelect device is intended to provide tissue for histological examination with partial or complete removal of imaged lesions. The scope of a histological abnormality is not able to be determined from it's mammographic appearance. Therefore, it is essential that the tissue margins be examined for margin involvement and completeness of removal in cases where the tissue sample is not found to be benign.

SiteSelect is to be used in conjunction with stereotactic mammographic imaging systems capable of determining position of lesion within breast tissue.

This device is used in conjunction with the SiteSelect Instrument Accessories, which are mounted on a stereotactic table and used with a stereotactic mammographic imaging system.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Russell D. Fragen Sr.

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993936

Prescription Use X OR Over-the-Counter Use _____
(Per 21 CFR 801.1091

(Optional Format 1-2-96)