K011575

AUG 1 7 2001

510(k) Summary of Safety and Effectiveness
May 18, 2001

1. Submitter

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2. Name of device

Common name: Biopsy Instrument
Trade name: SiteSelect Breast Biopsy Device
Classification name: Instrument, Biopsy

3. Devices to which substantial equivalence is claimed

510(k)#	Device	Manufacturer
K993936	SiteSelect Breast Biopsy Device	Imagyn Surgical
K972328	SiteSelect Breast Biopsy Device	Imagyn Surgical
K983296	ABBI	USSC
K954628	ABBI	USSC

4. Description of Device

SiteSelect Breast Biopsy System consists of the SiteSelect device and the Site Select table mount accessories. We have previously received clearance under 510(k) # K972328 for the 10mm and 15mm SiteSelect device. We have since received clearance under 510(k) #K993963 to expand the intended use. The Instrument Accessories have received clearance under 510(k) # K972328 and are currently on the market.

The SiteSelect device is provided sterile for single use only. It contains a Localization Needle, Localization Wire, a Stylet, and Cutting Cannula. The device is equipped with a Garrote Wire and Disc Blades to transect the specimen. The device is packaged in individual thermoformed blisters with peel off Tyvek® lid.

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5. Intended 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 its 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 a stereotactic mammographic imaging system 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.

6. Device compared to predicate device

The 22mm SiteSelect is substantially equivalent to like devices in commercial distribution and currently marketed by Imagyn Surgical and United States Surgical Corporation (USSC).

Imagyn Site Select and USSC devices are all used to obtain biopsies of the breast. These devices are used in conjunction with instrument accessories, which are used to mount the devices on a stereotactic table. The devices are used with stereotactic mammographic imaging systems, such as Fischer or Lorad prone stereotactic tables.

The 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.

The difference between the 22mm SiteSelect and currently marketed SiteSelect devices is the 22mm device has disc blades along with a garrote wire to transect tissue. The other difference is the method of trigger deployment. The triggers are pulled away from patient instead of being pushed forward

The construction, materials, and sterilization of the 22mm SiteSelect device is similar to the Imagyn Surgical SiteSelect devices currently on the market.

7. Clinical Performance Data

The 22mm SiteSelect clinical data was compared to data gathered on the current 15mm SiteSelect device. A total of 50 procedures (25-22mm and 25-15mm) were completed. The data in the following categories from both devices were comparable with no significant variances between the two:

- Patient population
- Procedure variables-procedure time, incision length, blood loss, use of electrocautery
- Discomfort level during the procedure
- Breast tissue appearance at follow up visit
- Specimens were suitable for pathological analysis

8. Conclusions drawn from clinical study

The 22mm SiteSelect device was shown to be safe for its intended use. In all clinical cases the device had accurate targeting of selected tissue and capture of adequate tissue specimen for histological analysis.

The clinical study showed the 22mm SiteSelect device was comparable to the 15mm SiteSelect device with no significant variances between the two.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Julie Powell
Vice President, Quality Assurance/Regulatory Affairs
Imagyn Surgical
A Division Of Imagyn Medical Technologies, Inc.
8850 M-89
P.O. Box 351
Richland, Michigan 49083

Re: K011575
Trade/Device Name: SiteSelect Breast Biopsy Device
Regulation Number: 876.1075
Regulatory Class: II
Product Code: KNW
Dated: May 18, 2001
Received: May 22, 2001

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 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). 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 requirements, 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) 594-4659. 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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

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

Enclosure

Ver/3-4/24/96

Applicant: Imagyn Surgical

5109(k) Number (if known): K011575

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 its 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 a stereotactic mammographic imaging system 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)
(Per 21 CFR 801.1091)

for Mark N Milhern

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

510(k) Number K011575