NOV 18 1999 K992813

Mammotome® Biopsy System
510(k) Summary of Safety and Effectiveness

Company
Ethicon Endo-Surgery, Inc.
4545 Creek Rd.
Cincinnati, OH 45242

Contact
Tamima Itani, Ph.D., RAC
Director, Regulatory Affairs

Date Prepared:
November 18, 1999

Name of Device
Trade Name: Mammotome® Biopsy System
Classification Name: Biopsy Needle

Predicate Devices:
Mammotome® Biopsy System
Powered Suction Pump
Tubing Clamp and Tubing Accessory
Arm Clamp

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

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

The extent of a 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.

Contraindication:
The Mammotome® Biopsy System is for diagnostic use only and is not indicated for therapeutic use.

Device Description
The Mammotome Biopsy System may use imaging guidance such as ultrasound, X-ray, and Computed Tomography (CT) to excise a diagnostic sample for diagnosis.
The Mammotome® Biopsy System allows the operator to sample breast tissue that has been identified as suspicious. Multiples samples, if necessary, can be taken without removing the needle. When imaging guidance is used, the operator may label or code the tissue as it is collected to correspond with the imaging display. Fluids can be delivered through the Mammotome® probe for the management of selected patient/procedure requirements.

Technological Characteristics
The technological characteristics are identical to those of the predicate device.

Performance Data
Clinical data from published literature is provided that supports the clarification in the indication for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Tamima Itani, Ph.D., RAC
Director, Regulatory Affairs
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242

Re: K992813
Trade Name: Mammotome® Biopsy System
Regulatory Class: II
Product Code: KNW
Dated: August 19, 1999
Received: August 20, 1999

Dear Dr. Itani:

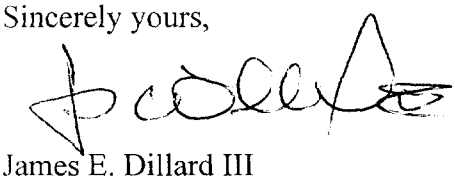
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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



James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K992813

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(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992813

Prescription Use
(Per 21 CFR 801.109)