

AUG 17 1999

K 991980

Section N

Mammotome[®] Hand-Held System 510(k) Summary of Safety and Effectiveness

Company

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

Contact

Tamima Itani, Ph.D.
Director, Regulatory Affairs

Date Prepared:

June 11, 1999

Name of Device

Trade Name: Mammotome[®] Hand-Held System
Classification Name: Biopsy Needle

Predicate Devices:

Mammotome[®] Biopsy Multi-Probe and Housing
Powered Suction Pump
Tubing Clamp and Tubing Accessory
Arm Clamp

Device Description

The Mammotome[®] Hand-Held System is a mechanical breast biopsy device used in incisional breast biopsy including microcalcifications, masses, spiculated masses, asymmetric densities, multi-focal disease, and diffused tissue.

The Mammotome[®] Hand-Held System consists of three major components, a disposable trocar tipped needle-like probe, a reusable holster/cable assembly, and a remote, reusable control module. The following accessories are also provided with the system: a disposable vacuum tubing set and canister, a footswitch, a support arm and a cart.

Intended Use

The Mammotome[®] Hand-Held System is indicated for use for incisional breast biopsy including microcalcifications, masses, spiculated masses, asymmetric densities, multi-focal disease, and diffused tissue.

The Mammotome[®] Hand-Held System is for diagnostic use only and is not indicated for therapeutic use.

Technological Characteristics

The Mammotome[®] Hand-Held System is a modification of the currently marketed Mammotome[®] Biopsy System. While it represents a refinement over the first generation Mammotome[®] with design, software and ergonomic enhancements for ease of use, the overall configuration, technology, materials and principles of operation of the proposed and marketed devices are equivalent.

The hand-held biopsy device, used with or without imaging modalities, provides for the diagnostic removal of tissue with fluid management through a combination of vacuum and radial cutting functions. The proposed and marketed devices contain the same primary components to achieve these functions: a probe, housing/holster, and a control module. The probe needle and cutter, which interface directly with the patient, are identical in both new and marketed devices.

In the proposed device, the housing is replaced by a holster and cable assembly and the motor resides in the control module. These physical changes make the probe lighter and more portable and facilitate user and patient interface.

The addition of a microprocessor and software allows the Mammotome[®] Hand-Held System to provide semi-automatic and automatic modes of operation for cutter advancement, vacuum, and specimen retrieval. Microprocessor control also provides closed-loop control to reduce dependence of cutter rotation and translation speed on user interaction or tissue variability.

In the marketed device, axial and lateral vacuum cannot be independently controlled. In the new device, axial and lateral vacuum can be controlled independently.

Performance Data

Preclinical testing was performed to ensure the device performs as intended. Testing demonstrated satisfactory performance in breast tissue biopsy.



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: K991980
Trade Name: Mammutome® Hand-Held System
Regulatory Class: II
Product Code: KNW
Dated: June 11, 1999
Received: June 14, 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,


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

Indications for Use Statement

510(k) Number: K 991980

Device Name: Mammotome® Hand-Held System

Indication for Use:

The Mammotome® Hand-Held System is indicated for use for incisional breast biopsy including microcalcifications, masses, spiculated masses, asymmetric densities, multi-focal disease, and diffused tissue.

The Mammotome® Hand-Held System is for diagnostic use only and is not indicated for therapeutic use.

Russell C. Pagano for 520

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K 991980

Prescription Use /
(Per 21 CFR 801.109)