

FEB 20 2004

K033700
1 of 2

Mammotome® EX Hand Held System

510(k) Summary of Safety and Effectiveness

Company

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

Contact

Carol Sprinkle, BSN, RN
Associate, Regulatory Affairs

Date Prepared:

November 24, 2003

Name of Device

Trade Name: Mammotome® EX Hand Held System
Classification Name: Biopsy Needle

Predicate Devices:

Mammotome® Hand Held System
Mammotome® Hand Held 8 Gauge Probe
Mammotome® Biopsy System

Device Description

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

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

Intended Use

The Mammotome EX Hand Held System is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality. The Mammotome EX Hand Held System is also intended to provide breast tissue for histologic examination with partial removal of a palpable abnormality.

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Technological Characteristics

The Mammotome EX Hand Held System is a modification of the currently marketed Mammotome Hand Held System. It represents a refinement in design, software and ergonomic enhancements for ease of use, however, the basic configuration, technology, materials and principles of operation of the proposed and marketed devices are equivalent.

The EX Hand Held biopsy device, used with or without imaging modalities, facilitates 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 similar in both new and marketed devices.

In the proposed device, the control module motors are bypassed and two mechanical cables are eliminated. Two small motors reside in the holster to power the cutter translation and rotation. These physical changes make the probe/holster easier to handle.

Software modifications allow the Mammotome EX Hand Held System to provide standard and rapid modes of operation for cutter advancement and specimen retrieval. A microprocessor provides closed-loop control to reduce dependence of cutter rotation and translation speed on user interaction or tissue variability.

Axial and lateral vacuum can still be controlled independently.

Performance Data

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 20 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Carol Sprinkle, BSN, RN
Associate, Regulatory Affairs
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242

Re: K033700

Trade/Device Name: Mammotome® EX Hand Held System
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: KNW
Dated: November 24, 2003
Received: November 25, 2003

Dear Ms. Sprinkle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

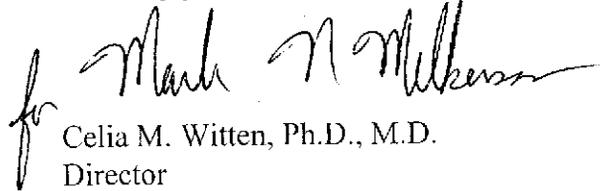
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Ms. Carol Sprinkle, BSN, RN

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,

A handwritten signature in black ink, appearing to read "for Celia M. Witten". The signature is written in a cursive style and is positioned to the left of the typed name.

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

Indications for Use Statement

510(k) Number: K 033700

Device Name: Mammotome® EX Hand Held System

Indications for Use:

The Mammotome Biopsy System is indicated to provide 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 Mammotome Biopsy System is intended to provide breast tissue for histologic examination with partial removal of a palpable abnormality.

The extent of a histologic abnormality cannot always be readily determined from palpation or imaged appearance. Therefore, the extent of removal of the palpated or 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.

In instances when a patient presents with a palpable abnormality that has been classified as benign through clinical and/or radiological criteria (e.g., fibroadenoma, fibrocystic lesion), the Mammotome Biopsy System may also be used to partially remove such palpable lesions. Whenever breast tissue is removed, histological evaluation of the tissue is the standard of care. 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.

for Mark A. Millers
(Division Sign-Off)
**Division of General, Restorative,
and Neurological Devices**

510(k) Number K033700

(Please do not write below this line -- continue on another page if necessary)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X OR Over-The-Counter-Use: _____