K093899

APR 29 2010

Section 5: 510(k) Summary

The following information is provided as required by 21 CFR § 807.87 for the Mammotome Biopsy System for Molecular Imaging 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990 the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

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Guaynabo, Puerto Rico 00969
Establishment Registration 3005075853

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Date of Submission: December 15, 2009

Proprietary Name: Mammotome® Biopsy System for Molecular Imaging

Common Name: Biopsy Instrument

Regulation: 21 CFR 876.1075

Regulatory Class: II

Product Codes: KNW

Predicate Device: Mammotome MR Biopsy System K042753

Device Description: The Mammotome Biopsy System for Molecular Imaging (MI) consists of four major components: a disposable Biopsy Probe; a disposable Universal Targeting Set; a reusable Holster, and a reusable Control Module. The following accessories are also provided with the system: a disposable vacuum tubing set and canister, a reusable control module cart, and a reusable interlock box.

Intended 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 the 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.

Technological Characteristics: The Mammotome Biopsy System for Molecular Imaging (MI) is a modification to the environment for use of the currently marketed Mammotome MR Biopsy System. It represents a refinement in device labeling to assure safety in a Molecular Imaging environment. The configuration, technology, and principles of operation of the proposed and marketed devices are equivalent. New product codes are assigned to the Probe and Universal Targeting Set components for user clarification and revised instructions for use are provided for the new intended use environment.

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Performance testing: There are no changes in the performance requirements of the subject device with respect to those of the predicate device. Specifically, the technology, biocompatibility requirements, control module device, and principles of operation of the subject and predicate devices are equivalent. Mitigation of risk associated with use of the subject device in the new environment ensures equivalent performance to that of the predicate device.

Clinical testing: Clinical testing was not performed in support of this submission.

Conclusion: The claim of substantial equivalence of the Mammotome Biopsy System for Molecular Imaging to the predicate device is based on the comparison of the intended use, product technical characteristics, and performance characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ethicon Endo-Surgery, LLC
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APR 29 2010

Re: K093899
Trade/Device Name: Mammotome® Biopsy System for Molecular Imaging
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: KNW
Dated: April 26, 2010
Received: April 27, 2010

Dear Asifa Vonhof:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use Statement

510(k) Number: To be assigned K093899

Device Name: Mammotome Biopsy System for Molecular Imaging

Indications for Use: The Mammotome Biopsy System is indicated to provide tissue samples for diagnostic sampling of breast abnormalities.

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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.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mkn

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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