K052246

AUG 2 2 2005

510(k) SUMMARY

Neothermia Corporation's en-bloc Biopsy System™

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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VP. Engineering
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Date Prepared: August 12, 2005

Name of Device and Name/Address of Sponsor

Common or Usual Name:	Electrosurgical Generator
Trade or Proprietary Name:	en-bloc Biopsy System™
Classification Name:	Electrosurgical Cutting & Coagulation Device & Accessories (21 C.F.R. § 878.4400) Biopsy Instrument (21 C.F.R. § 876.1075)

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Predicate Devices

Neothermia Corp.'s en-bloc Biopsy System (K003190, K021577, K020031, K042170, K050737) and the Ethicon Endo-Surgery Mammotome 510(k) K030472.

Intended Use

The en-bloc Biopsy System is indicated to provide tissue samples for diagnostic sampling of breast abnormalities.

The en-bloc Biopsy System is intended to provide breast tissue for histologic examination with partial or complete removal of an imaged abnormality.

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The en-bloc 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 palpable 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 en-bloc Biopsy System may also be used to partially remove such palpable lesions. Whenever breast tissue is removed, histologic 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 en-bloc is a percutaneous high frequency, automated, vacuum-assisted electrosurgical device used to remove tissue by automated electrosurgical cutting and simultaneous capture of an incised tissue volume. The Neothermia en-bloc ™ consists of a hand-held biopsy handle, upon which the single-use en-bloc Biopsy Probe is attached, with an integral cable to connect the handle to the control unit. The Probe™ contains two sets of active electrodes at its distal end – a precursor electrode and cutting/capture electrodes. The shaft of the Probe™ is encased in a stainless steel cannula. An outer plastic sleeve surrounds this stainless steel cannula and an annular gap between the sleeve and the cannula provides a conduit for vacuum-assisted removal of the gaseous products of electrosurgical cutting and any liquids (*e.g.*, blood) that may accumulate at the distal end of the Probe during the biopsy procedure. The vacuum also helps maintain the required cutting arc during automated tissue capture.

Substantial Equivalence

The probe with this manufacturing modification has the same intended use, principles of operation, and technological characteristics as the previously cleared predicate devices. The en-bloc probe with the manufacturing modification and its predicate devices are both electrosurgical devices used to biopsy breast tissue. The en-bloc probe with the manufacturing modification is substantially equivalent to Neothermia's cleared 10mm, 12mm, 15mm and 20mm en-bloc probes.

The modified Indications for Use are consistent with those of the predicate device (Mammotome). These Indications for Use are based upon the predicate devices ability to partially or completely remove imaged abnormalities. The en-block Biopsy System has been shown to be equally capable of partially or completely removing imaged abnormalities.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 2 2005

Mr. David Jacobs
VP Engineering
Neothermia Corporation
One Apple Hill, Suite 316
Natick, Massachusetts 01760

Re: K052246
Trade/Device Name: en-bloc Biopsy System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: August 16, 2005
Received: August 17, 2005

Dear Mr. Jacobs:

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.

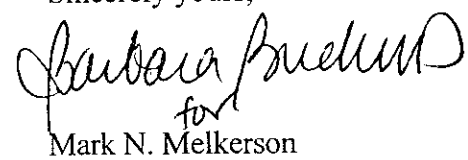
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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.

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 (240) 276-0115. 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,



for

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052246

Device Name: en-bloc Biopsy System

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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)

Barbara Buchman for MKM

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

510(k) Number K052246