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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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Date Prepared: January 3, 2002

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) and the 20mm Auto Suture ABBI Breast Biopsy System (K983296).

Intended Use

The en-bloc Biopsy System is intended for diagnostic sampling of breast tissue during a breast biopsy procedure.

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Technological Characteristics

The en-bloc is a high frequency, vacuum-assisted electrosurgical device used to remove tissue by 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.

Performance Data

Testing of the device was conducted on porcine tissue to evaluate the ability of the 20mm probe to cut and capture a predictable volume of tissue and to assess its suitability for post-biopsy pathology evaluation. It was determined that the 20mm probe is capable of obtaining intact, unfragmented biopsy specimens having a predictable diameter and length and suitable for post-biopsy histopathologic examination.

Substantial Equivalence

The Company's *en-bloc* Biopsy System™ with a 20mm probe covered by this submission is substantially equivalent to its *en-bloc* Biopsy System™ with a 10mm probe (K003190). Additionally, it is substantially equivalent to United States Surgical Corp.'s 20mm Auto Suture (ABBI) Breast Biopsy System (K9963825).

The modified *en-bloc* Biopsy System™ with a 20mm probe is identical to the cleared *en-bloc* Biopsy System™ with a 10mm probe except that the former is available with a 20mm disposable probe, as well as the cleared 10mm disposable probe.

With respect to the predicate device (*en-bloc* Biopsy System™ with a 10mm probe), the *en-bloc* Biopsy System™ with a 20mm probe has the same intended use, principles of operation, and technological characteristics.

With respect to the predicate device (20mm ABBI Breast Biopsy System), the *en-bloc* Biopsy System™ with a 20mm probe has similar intended use, both devices remove breast tissue for diagnostic biopsies. Both devices have similar principles of operation, and similar technological characteristics. Both devices remove a 20mm specimen.

Although there are minor differences in the characteristics of the 20mm *en-bloc* Biopsy System™ and its predicate devices, those differences do not raise new questions of safety or efficacy.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 7 2002

Ms. Sherrie Coval-Goldsmith
Vice President, Regulatory Affairs
and Quality Assurance
Neothermia Corporation
One Apple Hill, Suite216
Natick, MA 01760

Re: K020031
Trade/Device Name: En-Bloc Biopsy System™
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI and KNW
Dated: January 3, 2002
Received: January 4, 2002

Dear Ms. Coval-Goldsmith:

This letter corrects our substantially equivalent letter of March 27, 2002 regarding the product code.

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). 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 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

This letter will allow you to continue 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 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Miriam C. Provost

for 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

510(k) Number (if known): K020031

Device Name: en-bloc Biopsy System™

Indications for Use:

The en-bloc Biopsy System is intended for diagnostic sampling of breast tissue during a breast biopsy procedure.

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

_____ Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use____ (Per 21 C.F.R. 801.109)

(Optional Format 1-2-96)

Miriam C. Provost

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

510(k) Number K020031