K020276

APR 12 2002

510(k) Summary of Safety and Effectiveness Information

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

Contact Georgia C. Abernathy, MBA, RAC
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Date Prepared January 25, 2002

Device Name Trade Name: 8 Gauge MicroMark™ II Tissue Marker
Classification Name: Implantable Staple

Predicate Device MicroMark Clip

Device Description
The 8 Gauge MicroMark II Tissue Marker is a sterile, single patient use device comprised of a small stainless steel marker (clip) and a disposable Introducer and Applier. The Introducer consists of a flexible tube, a distal ramp, and a lateral port. The applier consists of a flexible shaft, a deployment mechanism and a handle. The marker is located at the distal end of the applier.

The 8 Gauge MicroMark II Tissue Marker is used with the currently marketed Ethicon Endo-Surgery, Inc. Mammotome® Hand-Held 8 Gauge Probe, which functions as a standard rigid coaxial Introducer.

The Tissue Marker is used with imaging guidance (stereotactic and ultrasound).

Indications for Use
The 8 Gauge MicroMark II Tissue Marker is indicated for use to attach to soft breast tissue at the surgical site during an open surgical breast biopsy or a percutaneous breast biopsy to radiographically mark the location of the biopsy procedure.

Technological Characteristics
Design changes made to the 8 Gauge MicroMark II Tissue Marker are an increase in the diameter of the Introducer. There are no changes to the implantable stainless steel marker (clip); it is identical to the marketed device.

Performance Data
Bench testing was performed to demonstrate that the device will perform as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 12 2002

Ms. Georgia C. Abernathy, MBA, RAC
Senior Regulatory Affairs Associate
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242-2839

Re: K020276
Trade/Device Name: 8 Gauge MicroMark™II Tissue Marker
Regulation Number: 878.4750
Regulation Name: Implantable Staple
Regulatory Class: II
Product Code: NEU
Dated: January 25, 2002
Received: January 28, 2002

Dear Ms. Abernathy:

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 and additionally 21 CFR 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

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

Enclosure

Indications for Use Statement

510 (k) Number (if known): K020276

Device Name: **8 Gauge MicroMark™ II Tissue Marker**

Indications for Use:

The 8 Gauge MicroMark II Tissue Marker is indicated for use to attach to soft breast tissue at the surgical site during an open surgical breast biopsy or a percutaneous breast biopsy to radiographically mark the location of the biopsy procedure.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

(Optional Format 3-10-98)

510(k) Number K020276