K970817

SEP 11 1997

APPENDIX V

Summary of Safety and Effectiveness

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The MicroMark clip is substantially equivalent to the BMI Surgical Staple Marker. The MicroMark clip has technologic characteristics which are substantially equivalent to the predicate device.

COMPANY AND CONTACT PERSON

Biopsys Medical, Inc. (BMI)
3 Morgan
Irvine, CA 92618

Mark A. Cole, Ph.D.
714-460-7800

DEVICE NAME

MicroMark™ Clip

NAME OF PREDICATE OR LEGALLY MARKETED DEVICE

BMI Surgical Staple Marker

STATEMENT OF INTENDED USE

The MicroMark intended use is to be applied to soft breast tissue during open or percutaneous procedures and radiographically mark the surgical location.

STATEMENT OF INTENDED USE OF PREDICATE/MARKETED DEVICES

The BMI Surgical Staple Marker's intended use is to be applied to soft tissue during open or percutaneous procedures; the staple may be used to radiographically mark the surgical location.

STATEMENT OF COMPARISON OF TECHNOLOGIC CHARACTERISTICS BETWEEN DEVICE AND PREDICATE DEVICE

The design, construction, materials, nominal specifications are identical to the marketed predicate device. The devices consist of a non absorbable material compatible with X-ray, i.e., clearly visible on a radiograph; the staple/markers are deployed with manual appliers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 11 1997

Ms. Irene Parker, R.N., M.B.A.
Director, Medical Affairs
Biopsys Medical, Inc.
3 Morgan
Irvine, California 92618

Re: K970817
Trade Name: MicroMark™ Clip
Regulatory Class: II
Product Code: GDW
Dated: June 18, 1997
Received: June 19, 1997

Dear Ms. Parker:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements , as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K970817

510(k) Number (if known):

Device Name: MicroMark™ Clip

Indications For Use: The MicroMark clip is intended to staple soft breast tissue at the surgical site during an open or percutaneous biopsy procedure and radiographically mark the location.

It is indicated for use to radiographically mark breast tissue following an open surgical breast biopsy or percutaneous breast biopsy.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
Per 21 CFR 801.109

(Division Sign-Off)
Division [illegible] Restorative Devices
510(k) Number K970817