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TAB 4

PREMARKET NOTIFICATION [510(K)] SUMMARY

October, 2002

Trade Name: Bio-MARK Resorbable Biopsy Site Marker
Bio-MARK Permanent Biopsy Site Marker

Common Name: Biopsy site marker

Classification Name: Instrument, biopsy (per 21 CFR section 878.4750)

Manufacturer's Name: Biopsy Sciences, LLC
6340 North Pinnacle Ridge Drive
Tucson, AZ 85718

Corresponding Official: Sharon Rockwell
Vice-President RA/QA
5582 Chalon Road
Yorba Linda, CA 92886
Phone: (714) 695-9269
Fax: (714) 779-0406

Predicate Device(s): J&J Ethicon MicroMark, Inrad UltraClip Tissue Marker, SenoRx Gel Mark Biopsy Site Marker, and Vivant Medical Biopsy Marker System

Device Description: The Bio-MARK biopsy site marker is made of a resorbable copolymer, a polyester derivative of lactic and glycolic acids. Polylactic/polyglycolic acid copolymers degrade and resorb *in vivo* by hydrolysis into lactic and glycolic acids, which are then metabolized by the body. The site markers are deployed through an applicator that fits in the J&J Ethicon Mammotome 11 gauge biopsy probe. The Bio-MARK device marks the site of biopsy tissue sample, and is visible for up to 6 weeks by x-ray, ultrasound and MRI. The body then metabolizes the marker over time. The Bio-MARK is sold in two styles: the Resorbable Bio-MARK is made of the copolymer only, the Permanent Bio-MARK is identical with the addition of a stainless steel component for permanent radiographic visibility.

Intended Use:

The Bio-MARK Resorbable Biopsy Site Marker is intended to mark tissue during a percutaneous breast biopsy procedure, and be visible under MRI, ultrasound and x-ray for at least 6 weeks.

The Bio-MARK Permanent Biopsy Site Marker is intended to mark tissue during a percutaneous breast biopsy procedure, and be visible under MRI and ultrasound for at least 6 weeks, and be permanently visible by x-ray.

Technological Characteristics:

Bio-MARK Site Markers are made of 75/25% poly(D,L-lactide-co-glycolide) copolymer into which a USP grade contrast agent has been incorporated to provide radiopacity. The markers are deployed into the biopsy needle tract using a hand held applicator with a two finger-push control rod that delivers a single marker.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2003

Ms. Sharon Rockwell
Vice President RA/QA
Biopsy Sciences, LLC
5582 Chalon Road
Yorba Linda, California 92886

Re: K023694
Trade Name: Bio-Mark Resorbable and Permanent Biopsy Site Markers
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: II
Product Code: NEU
Dated: January 22, 2003
Received: January 23, 2003

Dear Ms. Rockwell:

We have reviewed your Section 510(k) premarket 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) 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 (301) 594-4659. 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,

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

TAB 3

INDICATIONS FOR USE

510(k) Number: K023694

Device Name: Bio-MARK Resorbable Biopsy Site Marker, and
Bio-MARK Permanent Biopsy Site Marker

Indications for Use:

The Biopsy Sciences, LLC., Bio-MARK Resorbable Biopsy Site Marker is intended to mark tissue during a percutaneous breast biopsy procedure, and be visible under MRI, ultrasound and x-ray for at least 6 weeks.

The Bio-MARK Permanent Biopsy Site Marker is intended to mark tissue during a percutaneous breast biopsy procedure, be visible under MRI and ultrasound for at least 6 weeks, and be permanently visible by fluoroscopy.

(PLEASE DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K023694

☒ **Prescription Use** (per 21 CFR 801.109) or ☐ **Over-The-Counter Use**