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PREMARKET NOTIFICATION [510(K)] SUMMARY

Trade Name:	Biopsy Sciences Lung Biopsy Site Marker
Common Name:	Biopsy site marker
Classification Name:	Instrument, biopsy (per 21 CFR section 878.4750)
Manufacturer's Name:	Biopsy Sciences, LLC 3433 E. Fort Lowell Road Suite 103 Tucson, AZ 85716
Corresponding Official:	Sharon Rockwell Vice-President RA/QA 5582 Chalon Road Yorba Linda, CA 92886 Phone: (714) 695-9269 Fax: (714) 779-0406
Predicate Biopsy Site Markers:	Biopsy Sciences Bio-MARK Biopsy Site Marker, J&J Ethicon MicroMark, SenoRx Gel Mark Biopsy Site Marker, and Artemis CoreMARK/MegaMARK Biopsy Site Identifier.
Predicate Localization Devices:	Vivant Medical Biopsy Marker System, and Medical Device Technologies Aspiration and Injection Needle
Device Description:	Biopsy Sciences Lung Biopsy Site Markers are made of resorbable FocalSeal-L Surgical Sealant, an FDA approved hydrogel used on the surgical site during lung surgery. The FocalSeal-L hydrogel material degrades in a manner similar to absorbable sutures, via hydrolysis. The Site Markers mark the site of the biopsy tissue sample, which provides accurate visualization during surgical resection of the tumor. Lung biopsy procedures are performed by fine needle aspiration through a coaxial needle. When the fine needle aspiration device is removed, the delivery system is mated to the coaxial needle. The plunger of the delivery system is depressed, which accurately places the Site Marker in the biopsy tract.

Intended Use:

The Biopsy Sciences Lung Biopsy Site Marker is intended to provide accuracy in marking a biopsy location for visualization during surgical resection.

Technological Characteristics:

The Biopsy Sciences Lung Biopsy Sit Markers are made of desiccated hydrogel, which immediately expands on contact with fluids to fill the biopsy tract and accurately confirm the site of biopsy during surgical resection. The markers are deployed using a hand held applicator that mates to the coaxial needle used for the biopsy procedure.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 5 2004

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

Re: K041331
Trade/Device Name: Lung Biopsy Site Marker
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: II
Product Code: GDW
Dated: May 10, 2004
Received: May 19, 2004

Dear Ms. Rockwell:

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 (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

K041331

Indications for Use

510(k) Number (if known): K041331

Device Name: Lung Biopsy Site Marker

Indications For Use: The Biopsy Sciences, LLC., Lung Biopsy Site Marker is intended to provide accuracy in marking a biopsy location for visualization during surgical resection.

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K041331