K981477

JUN 10 1998

510(K) SUMMARY

1. SUBMITTER:

Medical Biopsy, Inc.
10800 Lyndale Avenue South
Suite 110
Bloomington, MN 55420
Telephone: 800-714-7788
Contact: Stephen M. Page, Regulatory Consultant
Date Prepared: April 23, 1998

2. DEVICE:

Classification Name: Instrument, Biopsy
Trade Name: Medical Biopsy Automatic Cutting Needle
Class II per 21 CFR 876.1075
The Product Code is 78 KNW

3. PREDICATE DEVICE:

The predicate device used to determine substantial equivalence for the Medical Biopsy **Automatic Cutting Needle** is the Manan Pro-Mag Automatic Biopsy Device (K914874).

4. DEVICE DESCRIPTION:

The Medical Biopsy Automatic Cutting Needle is a two-piece design consisting of a cannula and an obturator (stylet). The needles are made of 304 Stainless Steel. Etched markings have been incorporated along the shaft of both the cannula and the obturator, at intervals of 1cm, to guide depth of insertion. The distal end of the stylet is notched for tissue retention.

The proximal end of the Automatic Cutting Needle incorporates a plastic fitting for attachment to the "gun" portion of the Biopsy System, which houses, guides and manipulates the Automatic Cutting Needle during use. This "gun" component is sold separately by another company and is not covered within this 510(k) Premarket Notification.

When loaded into the "gun", the plastic spacer clip is removed from the end of the Automatic Cutting Needle. The hinged cover of the "gun" is then closed. At this point, the device is cocked, thereby spring-loading the Automatic Cutting Needle within. The distal end of the protruding Automatic Cutting Needle is then inserted into the body towards the target tissue. Once in the proximity of the target, the "gun" is fired and within a fraction of a second, the stylet penetrates the target tissue, which drops into the notch and is subsequently severed by the cannula which moves to recover the entire stylet tip. The gun/needle assembly is then removed from the body and the specimen is removed from the stylet, thus completing the procedure.

5. INTENDED USE:

The Medical Biopsy Automatic Cutting Needle is intended for use in obtaining samples of tissues or lesions.

6. COMPARISON OF CHARACTERISTICS:

The Medical Biopsy Automatic Cutting Needle and the currently marketed Manan Pro-Mag Automatic Biopsy Device are very similar in design:

a. Both devices consist of a two-piece design utilizing a cannula and a stylet.
b. The devices have the same Intended Use.
c. The devices are offered in the same sizes.
d. The devices are manufactured from the same material (stainless steel).
e. Both devices incorporate etched markings to guide depth of insertion.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 10 1998

Medical Biopsy, Incorporated
c/o Mr. Stephen M. Page
Regulatory Consultant
228 Hull Cove Farm Road
Jamestown, Rhode Island 02835

Re: K981477
Trade Name: Medical Biopsy Automatic Cutting Needle
Regulatory Class: II
Product Code: KNW
Dated: April 23, 1998
Received: April 24, 1998

Dear Mr. Page:

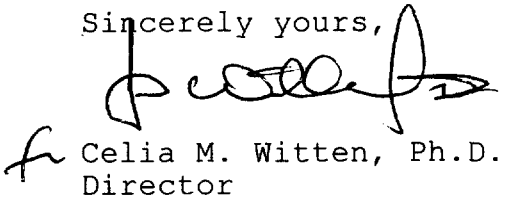
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 requirement, 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,



for 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

510(k) Number (if known): #K981477

Device Name: Medical Biopsy Automatic Cutting Needle

Indications For Use:

Medical Biopsy's **Automatic Biopsy Needle** is intended for use in obtaining samples of tissues or lesions from the Breast, Kidney, Prostate and Liver.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981477

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)