4445-310 S.W. 35th Terrace
Gainesville, Florida 32608
TEL: 352/338-0440 FAX: 352/338-0662

FEB 18 1998

K980226

510(k) SUMMARY

APPLICANT:	Medical Device Technologies, Inc. 4445-310 SW 35th Terrace Gainesville, FL 32608
CONTACT:	Karl Swartz Quality Assurance Manager
TELEPHONE:	(352)338-0440 fax (352)338-0662
TRADE NAMES:	Manan™ Pro-Mag Automatic Biopsy System
COMMON NAME:	Core Biopsy Device
CLASSIFICATION NAME:	Biopsy Instrument

SUBSTANTIAL EQUIVALENCE:

Company Name	Product Name	510(k) No.
Manan Medical Products	Manan Prostatic Biopsy Needle	K895897
Manan Medical Products	Pro-Mag Automatic Biopsy Instrument	K914874
Medical Device Tech.	Ultra-Core Biopsy Needles	K921418

DESCRIPTION OF DEVICE:

The Manan™ Pro-Mag Automatic Biopsy System is used to obtain multiple core samples from soft tissue such as the liver, kidney, prostate, breast, and various soft tissue lesions. It is not intended for bone.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 18 1998

Mr. Karl Swartz
Quality Assurance Manager
Medical Device Technologies, Incorporated
4445-310 SW 35th Terrace
Gainesville, Florida 32608

Re: K980226
Trade Name: Manan™ Pro-Mag Automatic Biopsy System
Regulatory Class: II
Product Code: KNW
Dated: December 18, 1997
Received: January 22, 1998

Dear Mr. Swartz:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are 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 devices, 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.

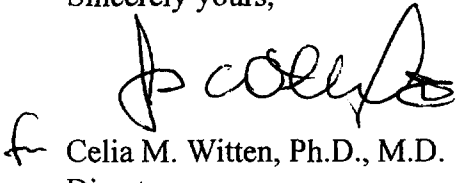
If your devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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. In addition, FDA may publish further announcements concerning your devices in the Federal Register. Please note: this response to your premarket notification submissions 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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

4445-310 S.W. 35th Terrace
Gainesville, Florida 32608
TEL: 352/338-0440 FAX: 352/338-0662

510(k) Number (if known): K980266

Device Name: Manan™

Indications for Use:

The Manan™ Pro-Mag Automatic Biopsy System is used to obtain multiple core samples from soft tissue such as the liver, kidney, prostate, breast, and various soft tissue lesions. It is not intended for bone.

(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 K980226

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)