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

K980211

FEB - 6 1998

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™ MRI Chiba Needle
MRI Spinal Needle
MRI Automatic Cutting Needle
MRI General Purpose Introducer Needle
MRI Techna-Cut Biopsy Needle
MRI Super-Core Biopsy Needle
MRI Breast Localization Needle
MRI Simon Breast Localization Needle

COMMON NAME: Hand-held biopsy needles.

CLASSIFICATION NAME: §878.4800 - Manual Surgical Instruments

SUBSTANTIAL EQUIVALENCE:

Company Name	Product Name	510(k) No.
Manan Medical Products	MRI Chiba Needle MRI Spinal Needle MRI Automatic Cutting Needle MRI General Purpose Introducer Needle MRI Techna-Cut Biopsy Needle MRI Super-Core Biopsy Needle MRI Breast Localization Needle MRI Simon Breast Localization Needle	K962977

DESCRIPTION OF DEVICE:

The biopsy needles can be used in MRI, Fluoroscopic, CT and Mammographic procedures to obtain biopsies of various tissues through a combination of cutting and/or aspirating.

The breast localization needles can be used in MRI, Fluoroscopic, CT and Mammographic procedures to obtain breast lesion tissue.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 6 1998

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

Re: K980211
Trade Name: Manan™ MRI Chiba, Spinal, Automatic Cutting, General Purpose Introducer, Techna-Cut Biopsy, Super-Core Biopsy, Breast Localization and Simon Breast Localization Needles
Regulatory Class: II
Product Code: KNW
Dated: January 20, 1998
Received: January 21, 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.

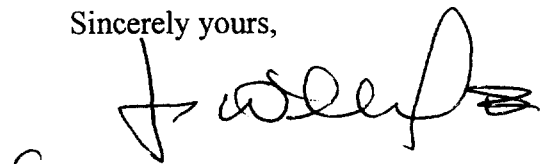
If your devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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): K980211

Device Name: Manan™ MRI Chiba Needle
MRI Spinal Needle
MRI Automatic Cutting Needle
MRI General Purpose Introducer Needle
MRI Techna-Cut Biopsy Needle
MRI Super-Core Biopsy Needle

Indications for Use:

These needles can be used in MRI, Fluoroscopic, CT and Mammographic procedures to obtain biopsies of various tissues through a combination of cutting and/or aspirating.

(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 K980211

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)

4446-310 S.W. 35th Terrace
Gainesville, Florida 32608
TEL: 352/338-0440 FAX: 352/338-0662

510(k) Number (if known): K980211

Device Name: Manan™ MRI Breast Localization Needle
MRI Simon Breast Localization Needle

Indications for Use:

The breast localization needles can be used in MRI, Fluoroscopic, CT and Mammographic procedures to obtain breast lesion tissue.

(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 K980211

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)