



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

JAN 30 1998

K980122

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™ Soft Tissue Biopsy Needles

COMMON NAME: Manual biopsy needles for soft tissue biopsies.

CLASSIFICATION NAME: Needle, Biopsy, Cardiovascular, No. 79DWO

SUBSTANTIAL EQUIVALENCE:

<u>Company Name</u>	<u>Product Name</u>	<u>510(k) No.</u>
Medical Device Technologies, Inc.	Manual Biopsy Needles	K944837
Manan Medical Products	Franseen Needle	K851831
Manan Medical Products	Greene Needle	K851835
Manan Medical Products	Westcott Needle	K851837
Manan Medical Products	Chiba Needle	K851838
Manan Medical Products	Trocar Needle	K852426
Manan Medical Products	Spinal Needle	K852427
Manan Medical Products	Turner Needle	K873208

DESCRIPTION OF DEVICE:

These devices are intended to be used in percutaneous soft tissue (pleura cavity and associated organs, abdominal cavity and associated organs, etc.) biopsies effected via the insertion of the device by a qualified physician, under guidance (CT, Ultrasound, Sequential Mammography, or Fluoroscopy), and manipulated in such a manner that a tissue specimen is retained within a collection orifice on the needle.





Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 30 1998

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

Re: K980122
Trade Name: MananTM Soft Tissue Biopsy Needles
Regulatory Class: II
Product Code: KNW
Dated: December 31, 1997
Received: January 14, 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.

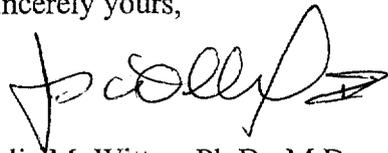
If your devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially-equivalent-determination-assumes-compliance-with-the-c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

Page 2 - Mr. Swartz

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,


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



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

510(k) Number (if known): K980122

Device Name: **Manan™ Soft Tissue Biopsy Needles**

Indications for Use:

The **Manan™ Soft Tissue Biopsy Needles** are intended to be used in percutaneous soft tissue (pleura cavity and associated organs, abdominal cavity and associated organs, etc.) biopsies effected via the insertion of the device by a qualified physician, under guidance (CT, Ultrasound, Sequential Mammography, or Fluoroscopy), and manipulated in such a manner that a tissue specimen is retained within a collection orifice on the needle.

(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

K980122

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

