



FEB 3 1998

K9P0196

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

**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™ Biopsy Set for *Bone and Bone Marrow*

**COMMON NAME:** Bone and/or bone marrow aspiration/biopsy needles

**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.	Bone Biopsy Needles	K961959
Manan Medical Products	Bone Marrow Biopsy	K890925
Manan Medical Products	Bone Biopsy Needle	K902177
Manan Medical Products	Pediatric Bone Marrow Needle	K962001

**DESCRIPTION OF DEVICE:**

These devices are intended for the purpose of harvesting bone and/or bone marrow specimens. They are inserted percutaneously, adjacent to the biopsy site. Access to the bone and/or bone marrow specimen(s) is achieved mechanically via cutting surfaces on the device. Harvesting of bone and/or bone marrow specimen(s) is accomplished both by mechanical and negative pressure (aspiration) which is created by attaching a syringe to a fitting on the outer cannula of the device. Specimen(s) are contained within the outer cannula during withdrawal from the patient.

In addition to the above, the pediatric bone marrow needle is intended for the purpose of obtaining access into medullary cavities for the purposes of initiating resuscitative infusion or for aspirating marrow in pediatric patients.





Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 3 1998

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

Re: K980196  
Trade Name: Manan™ Biopsy Set for Bone and Bone Marrow  
Regulatory Class: II  
Product Code: KNW  
Dated: January 19, 1998  
Received: January 20, 1998

Dear Mr. Swartz:

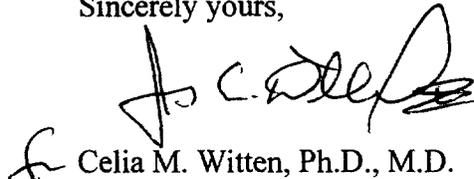
We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date 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): K980196

Device Name: **Manan™ Biopsy Set for Bone and Bone Marrow**

**Indications for Use:**

The Manan™ Biopsy Set for Bone and Bone Marrow is intended for the purpose of harvesting bone and/or bone marrow specimens. They are inserted percutaneously, adjacent to the biopsy site. Access to the bone and/or bone marrow specimen(s) is achieved mechanically via cutting surfaces on the device. Harvesting of bone and/or bone marrow specimen(s) is accomplished both by mechanical and negative pressure (aspiration) which is created by attaching a syringe to a fitting on the outer cannula of the device. Specimen(s) are contained within the outer cannula during withdrawal from the patient.

In addition to the above, the pediatric bone marrow needle is intended for the purpose of obtaining access into medullary cavities for the purposes of initiating resuscitative infusion or for aspirating marrow in pediatric patients.

(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

K980196

Prescription Use   
 (Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

