



K 98004

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

JAN - 9 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™ Co-Axial Introducer Needles

**COMMON NAME:** General introducer needle, biopsy needle

**CLASSIFICATION NAME:** §878.4800-Manual Surgical Instrument for General Use; Disposable  
Aspiration and Injection Needle

**SUBSTANTIAL EQUIVALENCE:**

<u>Company Name</u>	<u>Product Name</u>	<u>510(k) No.</u>
Manan Medical Products	Co-Axial Introducer Needles	K940024
Medical Device Technologies, Inc.	Hawkins-Akins Blunt Needle	K881957

**DESCRIPTION OF DEVICE:**

The Manan Co-Axial Introducer Needle is a general purpose introducer-type needle assembly intended for a range of biopsy applications of soft tissue. The device is composed of a cannula, available in various lengths in the range of 2 ins. to 8 in. and gauges of between 8 and 22, constructed of 304 stainless steel into which a stainless steel stylet fits. The molded hub holding the cannula is comprised of medical grade plastic. The combination of the stylet and needle terminates in a trocar-type needle point.





Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN - 9 1998

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

Re: K980004  
Trade Name: Manan™ Co-Axial Introducer Needles  
Regulatory Class: II  
Product Code: KNW  
Dated: December 31, 1997  
Received: January 2, 1998

Dear Mr. Swartz:

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.

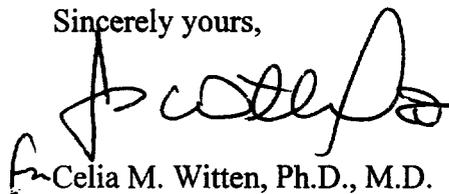
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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



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



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 TEL: 352/338-0440 FAX: 352/338-0662

510(k) Number (if known): K980004  
~~K97~~

Device Name: Manan™ Co-Axial Introducer Needles

Indications for Use:

The Manan™ Co-Axial Introducer Needle is intended for a range of biopsy applications of soft tissue.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
 (Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

[Signature]  
 (Division Sign-Off)  
 Division of General Restorative Devices  
 510(k) Number K980004

