



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

K974815

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™ Introducer

COMMON NAME: Guidewire introduction Needle(Sheath)

CLASSIFICATION NAME: §878.4200-Introduction/Drainage Catheter and Accessories

SUBSTANTIAL EQUIVALENCE:

<u>Company Name</u>	<u>Product Name</u>	<u>510(k) No.</u>
Manan Medical Products	Introducer Sheath/Needle	K961216

DESCRIPTION OF DEVICE:

The Manan Introducer Sheath/Needle is a 18 or 19 gauge trocar needle(Surgical grade 304 Stainless Steel) inside a 5 French radiopaque Teflon sheath. The sheath is tapered down to the trocar needle. The sheath accepts up to and including a .038 in. diameter guidewire. The usable length of this assembly is up to 20 cm.





Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

JAN - 9 1998

Re: K974815
Trade Name: Manan™ Introducer
Regulatory Class: II
Product Code: FGE
Dated: December 18, 1997
Received: December 23, 1997

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.

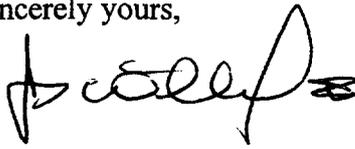
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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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 Gainesville, Florida 32608
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510(k) Number (if known): K974815

Device Name: Manan™ Introducer Sheath/Needle

Indications for Use:

The Manan™ Introducer Sheath/Needle is for the introduction of a .038 in. guidewire used in abscess, biliary, nephrostomy, and other fluid collection drainage procedures.

(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 K974815

Prescription Use X
 (Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

