K980005
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MEDICAL DEVICE TECHNOLOGIES INC
4445-310 S.W. 35th Terrace
Gainesville, Florida 32608
TEL: 352/338-0440 FAX: 352/338-0662

JAN 30 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™ D Bag

COMMON NAME: Biliary (fluid drainage) collecting bag

CLASSIFICATION NAME: §876.5010-Biliary Catheters and Accessories

SUBSTANTIAL EQUIVALENCE:

Company Name	Product Name	510(k) No.
Manan Medical Products	D Bag	K961986/K963849

DESCRIPTION OF DEVICE:

The Manan D Bag is a 600 ml drainage bag to be used for biliary, nephrostomy and other fluid drainage procedures. The bag has a twist close closure at the bottom for allowing the fluid to drain out. The bag is manufactured from either SP 2255, (an Ethylene Methyl Acrylate Copolymer film) or PVC. The catalog number will be DBAG 600 when Ethylene Methyl Acrylate Copolymer film is used, and DBAG 600V when PVC is used. The bag itself has a backing made from a non-woven polyester. This backing provides comfort for the patient. This backing will be optional on the product. A tube made from silicon is attached to the bag at one end and has a luer lock at the other for attaching to the drainage catheter. The preferred length of this tube is 30 ins. Other lengths between 24 and 42 ins. could possible be used in the future. An adjustable Velcro strap with some elasticity is supplied with the bag so it can be hung about the patient's waist, leg or shoulder.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 30 1998

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

Re: K980005
Manan™ D Bag (Biliary Drainage Bag)
Dated: December 29, 1997
Received: January 2, 1998
Regulatory Class: II
21 CFR 876.5010/Procode: 78 EXF

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 requirement, 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) 594-4613. 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K980005

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

510(k) Number (if known): K97

Device Name: Manan™ D Bag

Indications for Use:

The Manan™ D Bag is for nephrostomy, abcess and other drainage collection.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R Watkins
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K980005

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)