K964757
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510(k) Summary

SUBMITTER:

ContiMed, Inc.
7680 Golden Triangle Drive
Eden Prairie, MN 55344
612-829-4057

JUN 25 1997

DATE SUMMARY PREPARED: 06-19-97

TRADE NAME: ContiDrain™ Catheter & Accessories
COMMON NAME: Urological catheter

SUBSTANTIALLY EQUIVALENT TO: The ContiDrain™ Catheter is substantially equivalent to the Foley catheter indications for use. The ContiDrain™ Catheter is substantially equivalent to the technological characteristics for retention to the Bard Figure Four Ureteral Stent and pigtail ureteral stents (K861478). The ContiDrain™ Catheter employs the same type of open-sided flow channels as are found in the Tower peripheral stent. The ContiDrain™ Catheter is substantially equivalent to the materials of the Bard Polyurethane (Flexible tip) Ureteral Catheters (K950300).

DESCRIPTION OF THE DEVICE: The ContiDrain™ Catheter is an indwelling urinary catheter with the same indication for use and function as a conventional Foley catheter. Like a Foley catheter, the ContiDrain™ Catheter is indicated for continuous urine drainage. Both devices use a tubular catheter to pass urine from the bladder through the urethra and meatus into a urinary drainage bag. Both devices also have a mechanism for retention in the bladder. The ContiDrain™ Catheter has two design features that are different from the conventional Foley catheter. The ContiDrain™ Catheter incorporates two design features found in conventional ureteral stents. These features involve the methods of urine flow and of retention in the bladder.

INDICATIONS FOR USE: The ContiDrain™ Catheter is indicated for continuous urine drainage.

SUPPORTING INFORMATION:

BENCH TESTING: Flow and retention bench testing that has been conducted according to (modified) methods and fixtures described in the Foley and stent (draft) ASTM methods.

CLINICAL EVALUATION: The ContiDrain™ Catheter Feasibility Study protocol has been cleared as a non-significant risk clinical study by the FDA and by three IRB-centers with three investigators. The feasibility study, lasting less than 15 minutes per patient, evaluated how well the healthcare professional can insert and remove the 16 Fr catheter and if the catheter will remain in place during the evaluation period. Nine adult male patients in three centers presenting with either an indwelling Foley catheter or at the urodynamic lab for routine evaluation were enrolled. Data from these centers indicate that retention is adequate when the catheter is properly secured. Furthermore, the healthcare professionals have reported satisfactory insertion and removal, with generally favorable acceptance from the patients. Urine drainage was evaluated in one patient and found to be good.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 25 1997

Claude Tihon, Ph.D.
President
ContiMed, Inc.
7680 Golden Triangle Drive
Eden Prairie, Minnesota 55344

Re: K964757
ContiDrain™ Catheter
Dated: April 18, 1997
Received: April 21, 1997
Regulatory class: II
21 CFR §876.5130/Product code: 78 EZL

Dear Dr. Tihon:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4616. 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

510(k) Number (if known) K964757

Device Name: ContiDrain™ Catheter by ContiMed, Inc

Indications for Use:

The ContiDrain™ Catheter is indicated for continuous urine drainage.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over -The-Counter Use _____

(Optional Format 1-2-96)

Robert R Ratliff

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K964757