MAR 2 9 2006

510(k) Summary

1. SPONSOR

Med-Conduit Inc.
18 Derby Lane
Tyngsboro, MA 01879

Contact: Gerald G. Bousquet, M.D.

Date Prepared:

2. DEVICE NAME

Proprietary Name:	PD Cath
Common/Usual Name:	Skin Port Catheter
Classification Name:	Long-Term PD Catheter
Classification:	

3. PREDICATE DEVICES

Dermaport™ Access Device--K894131

Missouri Catheter—K874650

4. DEVICE DESCRIPTION

The PD Cath is a radiopaque silicone, single lumen catheter used to insert and remove peritoneal fluid. The fixed Dacron cuff allows for tissue ingrowth for long-term placement. A flexible silicone overtube is permanently bonded to the lumen passages and the cuff to insulate the cuff from forces applied to the external or internal lumens.

5. INTENDED USE

The PD Cath is indicated for use in attaining long term peritoneal access for peritoneal dialysis via the peritoneum. The catheter is intended for implantation dwell time of greater than 30 days.

6. SUBSTANTIAL EQUIVALENCE

The PD Cath is substantially equivalent to a combination of its predicate devices in terms of intended use, design, material type, performance, and method of sterilization.

7. PERFORMANCE TESTING

Information submitted in this premarket notification includes in vitro performance data for the PD Cath including flow rate and tensile strength that is substantially equivalent to the legally marketed devices.

Clinical data was not deemed necessary since in vitro testing was sufficient to demonstrate safety and efficacy by way of comparison to legally marketed predicate device intended for peritoneal dialysis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 9 2006

Gerald G. Bousquet, M.D.
Med-Conduit, Inc.
18 Derby Lane
TYNGSBORO MA 01879

Re: K053123
Trade/Device Name: PD Cath/Skin Port
Regulation Number: 21 CFR §876.5630
Regulation Name: Peritoneal dialysis system and accessories
Regulatory Class: II
Product Code: FJS
Dated: February 7, 2006
Received: February 16, 2006

Dear Dr. Bousquet:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K053123

Indications for Use

510(k) Number (if known): K053123

Device Name: PD Cath/Skin port

Indications For Use: The PD Cath is indicated for use in attaining long term peritoneal access for peritoneal dialysis. The catheter is intended for implantation dwell time of greater than 30 days.

Prescription Use ____X__ (Part 21 CFR 801 Subpart D) ~~AND~~/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(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 Reproductive, Abdominal, and Radiological Devices
510(k) Number K053123