

K970159

## 510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is \_\_\_\_\_ SEP - 5 1997

### Applicant Information

<i>Date Prepared</i>	January 6, 1997
<i>Name</i>	MEDIGROUP, Inc. (Division of Janin Group, Inc.)
<i>Address</i>	615 Enterprise Street, Aurora, IL 60504-8138
<i>Contact Person</i>	Pamela L. Swatkowski
<i>Phone Number</i>	(630) 585-1991
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### Device Information

<i>Trade Name</i>	Flex-Neck™ PD Catheter
<i>Common Name</i>	Peritoneal Catheter
<i>Classification Name</i>	Peritoneal Catheter; long-term, indwelling

### Equivalent Device

<i>Name</i>	Peritoneal Dialysis Catheter Swan Neck Peritoneal Dialysis Catheter Tenckhoff Catheter
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### Device Description

The current Tenckhoff peritoneal catheter is generally successful in providing peritoneal access for fluid infusion and drainage. The Flex-Neck™ PD Catheter is extruded of medical long-term implantable silicone basically identical to the existing Tenckhoff peritoneal catheters. All these peritoneal catheters include one or two Dacron® cuffs, the "deep" cuff in the abdominal musculature and the "superficial" cuff near the skin exit site of the catheter. Ingrowth of fibrous tissue over a few weeks period results in a thick fibrous plug preventing passage of bacteria around the Dacron® cuff. The coiled or straight intraperitoneal portion of the catheters contains multiple holes: 0.75mm in the Flex-Neck™ and 1.0mm in the Tenckhoff. Generally, the smaller the hole, the less likely omentum is to become trapped within the holes. During infusion of PD fluid, most of the flow is through the tip of the catheter. During outflow of the fluid, the soft surfaces of the peritoneum over bowel loops and omentum may be drawn to the tip, however, outflow continues through the multiple side holes.

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The Flex-Neck™ PD Catheter can be inserted via conventional surgical methods or via the Quill® Guide of the Y-TEC® peritoneoscopic system.

### Intended Use

If the patient is a suitable candidate for peritoneal dialysis (PD) therapy, the Flex-Neck™ PD Catheter can be implanted either surgically or peritoneoscopically. The only contraindication to implantation of the Flex-Neck™ PD Catheter is if the patient is not a candidate for peritoneal dialysis. Numerous prior surgeries or suspected or documented intraperitoneal adhesions may be relative contraindications to PD. However, since the Y-TEC® System of peritoneoscopic implantation enables inspection of the peritoneum to confirm the presence of adhesions and to avoid them, all patients who are suitable for PD can receive this catheter.

### Comparison to Predicate Device

The following table displays the similarities and differences of the new device to the legally marketed device to which equivalency is claimed.

Characteristics Compared	Subject Device <i>Flex-Neck™ PD Catheter</i>	Predicate Device <i>Swan Neck™ Coiled</i>	Predicate Device <i>Tenckhoff</i>
1. Material: Catheter	Silicone	Silicone	Silicone
2. Material: Cuff	Dacron® Felt	Dacron® Felt	Dacron® Felt
3. # of Cuffs	1-2	1-2	1-2
4. Outside Diameter (OD)	3.5 - 5.0 mm	5.0 mm	5.0 mm
5. Inside Diameter (ID)	2.0 - 3.5 mm	2.7 mm	2.7 mm
6. Length	Varies 43-62	Varies 43-62	Varies 43-62
7. Radiopaque stripe	Blue	White	White
8. Distal (deep) cuff location	within the rectus	within the rectus	within the rectus
9. Diameter of inflow/outflow holes	0.75 mm	1.00 mm	1.00 mm
10. Proximal (superficial) cuff location relative to distal cuff	Varies	Varies	Varies
11. Exit site direction (location) choices relative to implantation site	Any place between lateral and caudal 30° - 90° bend	Caudal 60° nominal	0-15° straight to slight lateral
12. Durometer	50	65	70 - 65



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP - 5 1997

Ms. Pamela L. Swatkowski  
Quality Assurance & Regulatory Affairs Manager  
MEDIGROUP, Inc.  
(Division of Janin Group, Inc.)  
615 Enterprises Street  
Aurora, Illinois 60504-8138

Re: K970159  
Flex-Neck™ PD Catheter  
Dated: June 6, 1997  
Received: June 9, 1997  
Regulatory class: II  
21 CFR §876.5630/Product code: 78 FJS

Dear Ms. Swatkowski:

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

510(k) Number (if known): K970159

Device Name: Flex-Neck™ PD Catheter

Indications for Use:

If the patient is a suitable candidate for peritoneal dialysis (PD) therapy, the Flex-Neck™ PD Catheter can be implanted either surgically or peritoneoscopically. The only contraindication to implantation of the Flex-Neck™ PD Catheter is if the patient is not a candidate for peritoneal dialysis. Numerous prior surgeries or suspected or documented intraperitoneal adhesions may be relative contraindications to PD. However, since the Y-TEC® System of peritoneoscopic implantation enables inspection of the peritoneum to confirm the presence of adhesions and to avoid them, all patients who are suitable for PD can receive this catheter.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R. Sattley  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

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Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use