

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 _____.

Applicant Information

<i>Date Prepared</i>	March 15, 1999
<i>Name</i>	MEDIGROUP, Inc. (Division of Janin Group, Inc.)
<i>Address</i>	615 Enterprise Street, Aurora, IL 60504-8138
<i>Contact Person</i>	John A. Navis
<i>Phone Number</i>	(630) 585-1991
<i>Fax Number</i>	(630) 585-5480

Device Information

<i>Trade Name</i>	Ash Advantage™ Peritoneal 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 Flex-Neck™ 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 Ash Advantage™ Peritoneal 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 Tenckhoff catheter contains multiple 1.0 mm 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.

The Ash Advantage™ Peritoneal Catheter has been developed with a thin trans-abdominal tube connecting in an inverted “T” shape to a cylindrical portion which changes to longitudinal flutes (grooves) for ports, which rest against the parietal peritoneum. The Ash Advantage™ Peritoneal Catheter can be inserted via conventional surgical methods or via the Quill® Guide of the Y-TEC® peritoneoscopic system, which is used to insert the standard Tenckhoff dialysis catheters. (See “Implantation Instructions” in Appendix B.) The fixed position of the intraperitoneal portion of this catheter is designed to prevent outward migration of the deep and superficial cuffs, avoiding pericatheter hernias, pericatheter leaks, and erosion and infection of the subcutaneous cuff.

Though this Ash Advantage™ Peritoneal Catheter is a novel design for peritoneal catheters used in dialysis, it actually represents a simple combination of two catheters which are currently utilized in medical practice for peritoneal access. The portion of the catheter outside the peritoneum is exactly like the Tenckhoff catheter, with deep and superficial cuffs. The fluted portion within the abdomen is exactly like a drain used to remove fluid from the peritoneum after surgery, the Blake™ Drain by Johnson & Johnson. The Ash Advantage™ Peritoneal Catheter is extruded of medical long-term implantable silicone basically identical to existing catheters and drains. The extrusions are bonded to form the inverted “T” which is then reinforced with molded silicone. The Ash Advantage™ Peritoneal Catheter is substantially equivalent to currently marketed devices.

Intended Use

If the patient is a suitable candidate for peritoneal dialysis (PD) therapy, the Ash Advantage™ Peritoneal Catheter can be implanted either surgically or peritoneoscopically. The only contraindication to implantation of the Ash Advantage™ Peritoneal 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 Table

Characteristics Compared	New Device <i>Ash Advantage™ Peritoneal Catheter</i>	Predicate Device <i>Flex-Neck™ Coiled Medigroup</i>	Predicate Device <i>Swan Neck™ Coiled Kendall</i>	Predicate Device <i>Tenknon™ Kendall</i>	Predicate Device <i>LifePath™ Catheter Kendall</i>	Predicate Device <i>Blake™ Drain Johnson & Johnson</i>
1. Material: Catheter	Silicone	Silicone	Silicone	Silicone	Silicone	Silicone
2. Material: Cuff	Dacron® Felt	Dacron® Felt	Dacron® Felt	Dacron® Felt	Dacron®	N/A
3. Number of Cuffs	2	1-2	1-2	1-2	2	None
4. Outside Diameter	3.5 mm to 7.0 mm	3.5 mm to 7.0 mm	5.0 mm	5.0 mm	5.0 mm	4.5 mm
5. Inside Diameter	2.0 mm to 5.5 mm	2.0 mm to 5.5 mm	2.7 mm	2.7 mm	2.7 cm	3.0 mm (propor.)
6. Length [Proximal end to post distal (deep) cuff]	variable 24.0 cm to 30.0 cm (trans-abdominal tube)	variable 29 cm to 27 cm	28.0 cm	28.5 cm	28.0 cm	N/A (no deep cuff)
7. Intraperitoneal portion [from deep cuff to end of intraperitoneal portion]	30.0 cm (includes both fluted sections)	32.0 cm	34.0 cm	34.0 cm	5.1 cm diameter discs	N/A (no deep cuff)
8. Radiopaque stripe	Yes - Blue	Yes - Blue	Yes - White	Yes - White	Yes - White	Yes - White
9. Distal (deep) cuff location	within the rectus	within the rectus	within the rectus	within the rectus	within the rectus	N/A
10. Proximal (superficial) cuff location relative to distal cuff	6.0 cm (standard adult)	6.0 cm (standard adult)	5.2 cm (standard)	6.0 cm (standard)	6.22 cm (standard)	N/A
11. Exit site direction (location), choices relative to implantation site	any place between lateral and caudal 30° - 90° bend	any place between lateral and caudal 30° - 90° bend	Caudal 60° nominal	0-15° straight to slight lateral	downward caudally	N/A



JUN 25 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Mr. John A. Navis
President
Medigroup, Inc.
615 Enterprise Street
Aurora, IL 60504-8138Re: K991042
Ash Advantage™ Peritoneal Catheter
Dated: March 26, 1999
Received: March 29, 1999
Regulatory Class: II
21 CFR §876.5630/Procode: 78 FJS

Dear Mr. Navis:

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 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). 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) 594-4613. 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/dsma/dsmamain.html>".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting 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): _____

Device Name: Ash Advantage™ Peritoneal Catheter

Indications for Use:

The Ash Advantage™ Peritoneal Catheter is intended to provide access for passage of dialysate during chronic peritoneal dialysis (PD) such as Continuous Ambulatory Peritoneal Dialysis (CAPD). If the patient is a suitable candidate for (PD) therapy, the Ash Advantage™ Peritoneal Catheter can be implanted either surgically or peritoneoscopically. The only contraindication to implantation of the Ash Advantage™ Peritoneal 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)

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

David A. Ferguson
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K991042