SEP 17 2003

6. SMDA Information

6.1. 510(k) Summary of Safety and Effectiveness

6.1.1. Basic Data

Date Prepared:	April 24, 2003
Company:	MEDIGROUP, Inc.
Contact:	John A. Navis, President
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6.1.2. Device Information:

Classification Name:	Peritoneal Catheter; long-term, indwelling
Common Name:	Peritoneal Catheter

6.1.3. Predicate Device

Flex-Neck™ Peritoneal Catheter, 510 (k) 970159.

6.1.4. Intended Use & Device Description

6.1.4.1. The current Flex-Neck™ catheters (510 (k) 970176) are designed for the typical adult or infant patient who needs peritoneal dialysis (PD) therapy. To facilitate different patient sizes and physiques, there currently are 2 styles (internally coiled and straight) and 5 different adult sizes at 62 cm long and 2 pediatric sizes at 42 cm long. All these catheters share the same outside diameter (OD, 5.1 mm) and the same inside diameter (ID, 3.5 mm). The actual lengths and the location of the polyester cuffs are the primary variables. (See Appendix B.)

The Flex-Neck™ Catheter, Infant (part number CF-4240 and CF-4245) is intended for infants. (The overall length remains at 42 cm, but the OD and ID are smaller – 3.7 mm and 2.5 mm, respectively. (See Appendix B.)

6.1.4.2. This device consists of the following components:

a. 1-Flex-Neck™ Catheter, Infant, made of long-term, implantable grade silicone tubing with radiopaque strip and 1 or 2 polyester cuffs. All components are made of the same materials as the Flex-Neck™ Catheter, Adult and Pediatric. The Infant catheter also has 4 rows of side holes punched into the tubing at the distal end to facilitate inflow and outflow of dialysate. (See Appendix B for additional details.)

b. 1-Right hand and 1-left hand tunnel marking stencils to mark and guide and thereby assist the implanting doctor to make a sound subcutaneous tunnel for the catheter.
c. 1-Surgical grade marking pen
d. 1-Catheter connector, plastic
e. 1-Catheter cap, plastic
f. 1-Tube (20 cc) of water-soluble lubricating gel

6.1.5. Testing

Functional testing has been performed to demonstrate mechanical integrity and retention.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 17 2003

Mr. John A. Navis
President
MEDIGROUP, Inc.
505 Weston Ridge Drive
NAPERVILLE IL 60563-3932

Re: K031351
Trade/Device Name: Flex-Neck™ PD Catheter, Infant; Part #CF-4240 and CF-4245
Regulation Number: 21 CFR §876.5630
Regulation Name: Peritoneal dialysis system and accessories
Regulatory Class: II
Product Code: 78 FJS
Dated: June 23, 2003
Received: June 24, 2003

Dear Mr. Navis:

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 (PMA), it may be subject to 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.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

K031351

7. **Indications for Use**

510(k) Number: K031351

Device Name: Flex-Neck™ PD Catheter, Infant

If the patient is a suitable candidate for peritoneal dialysis (PD) therapy and is too small for the current Flex-Neck™ catheters, the Flex-Neck™ Catheter, Infant, can be implanted either surgically, peritoneoscopically or percutaneously. The only contraindication to implantation of the Flex-Neck™ PD Catheter, Infant, is if the patient is not a candidate for peritoneal dialysis.

(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)

(Optional Format 1-2-96)

David A. Lynn

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031351