K071167

AUG 31 2007

page 1 of 1

MEDIGROUP, Inc.

510(k) Summary

Basic Information

Submitter:	Medigroup, Inc. 14 A Stonehill Road Oswego, IL 60543
Establishment Registration Number:	#1450420
Contact:	John A. Navis, President
Telephone:	(630) 554-5533
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Date of Submission	April 13, 2007

Device Information

Trade Name:	Flex-Neck® ExxTended™ PD Catheter & Accessories
Common Name:	Peritoneal Dialysis Catheter & Accessories
Classification Name:	78 FJS, accessory.
Class:	II

Predicate Devices

510(k) K950042 Swan-Neck™ Presternal PD Catheter issued Dec 15, 1995
510(k) K970159 Flex-Neck® PD Catheter issued Sept 5, 1997
510(k) K823331 Tunnelor issued Jan 26, 1983

Product Description

This device consists of a two-part peritoneal dialysis catheter and accessories. The catheter is made of long-term, implantable grade silicone tubing with a radiopaque strip, and two cuffs made of polyester felt. The coiled lower catheter section (with one rectus cuff) connects to an arcuate upper catheter section (with one exit cuff) via a tube-to-tube titanium connector (included), secured with a non-absorbable nylon suture (not included). Also included in the catheter package is a set of stencils (right and left) to assist the physician to locate the optimum primary implantation site and the optimum catheter exit site below the sternum. (Note: In addition to being packaged with each catheter, this stencil set will be sold sterile, packaged by itself, so the physician or other qualified personnel can use it in a clinical setting prior to the implantation.) Also included in the packaging will be a surgical grade marking pen, a tape measure, a plastic catheter connector and cap, a packet of water-soluble lubricating gel, and an ExxTended™ tunneling tool.

Intended Use

The Flex-Neck® ExxTended™ catheter is designed for adults for whom peritoneal dialysis has been decided to be the mode of treatment by a physician. It is intended for use for the 20-25% of peritoneal dialysis patients who are poor candidates for conventional Swan-Neck™ or Flex-Neck® catheters due to their body habitus, belt line, restricted dexterity, bathing preferences, or body folds.

MEDIGROUP, Inc.
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 1 2007

Mr. John A. Navis
President
Medigroup, Inc.
14 A Stonehill Road
OSWEGO IL 60543-9400

Re: K071167
Trade/Device Name: Flex-Neck® ExxTended™ Peritoneal Dialysis Catheter & Accessories
Regulation Number: 21 CFR §876.5630
Regulation Name: Peritoneal dialysis system and accessories
Regulatory Class: II
Product Code: FJS
Dated: August 15, 2007
Received: August 16, 2007

Dear Mr. Navis:

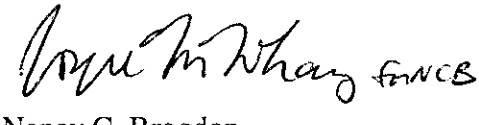
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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 (21 CFR Part 807); 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 the labeling regulation, please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number K071167

Device Name: Flex-Neck® ExxTended™ Peritoneal Dialysis Catheter & Accessories

Indications For Use:

If a patient is a suitable adult candidate for peritoneal dialysis (PD) therapy, the Flex-Neck® ExxTended ™ peritoneal dialysis catheter can be implanted either surgically, laparoscopically, or peritoneoscopically for acute or chronic peritoneal dialysis. Stencils sold with the device, and marketed separately, will be used to assist the physician to locate the optimum primary implantation site and the optimum catheter exit site for the Flex-Neck® ExxTended™ Catheter.

Prescription Use ✓ (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 K071167