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7. SMDA Information

7.1. 510(k) Summary of Safety and Effectiveness

7.1.1. Basic Data

Date Prepared:	June 18, 2001
Company:	MEDIGROUP, Inc.
Contact:	John A. Navis, President
Phone:	(630) 428-4143
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7.1.2. Device Information:

Classification Name:	Peritoneal Catheter Accessory
Common Name:	Catheter Extender/Repair Kit

7.1.3. Predicate Device

This device is substantially equivalent to the Extender/Repair Kit marketed by Kendall, Quinton #8888717001, 510(k) # unknown.

7.1.4. Device Description & Intended Use

This device consists of four components per kit, a double male connector, a catheter connector, a cap and a 20cm long silicone tube, to be assembled in an aseptic manner by qualified personnel.

The intended role of this device is to be used with Flex-Neck catheters and with Ash Advantage catheters in the event one of the two situations described below should occur.

7.1.4.1. Extender Application

In some patients, the external portion of the PD catheter may be too short for them to comfortably use. For example, obese patients may need an extender kit to be able to work with the external part of the catheter. Other patients may require the external end of the catheter to be more centrally located than it normally might be.

7.1.4.2. Repair Application

If a peritoneal dialysis catheter develops a fracture in its external portion, the catheter must be trimmed to eliminate the fracture. Doing so, by definition, will shorten the catheter and may make it impractical or difficult or even unsuitable for use. Rather than replace

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the entire catheter, it is desirable to retain the catheter by extending the external part of the catheter with new tubing.

In either situation, this device enables trained medical staff to extend and/or repair the external part of an existing Flex-Neck catheter or Ash Advantage catheter by adding a 20 cm long tube to the existing and /or remaining catheter tubing.

7.1.5. 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

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Mr. John Navis
President
MEDIGROUP, Inc.
Division of Janin Group, Inc.
505 Weston Ridge Drive
NAPERVILLE IL 60563

Re: K012502
Trade/Device Name: Medigroup Catheter Extender/Repair Kit, CE-1350
Regulation Number: 21 CFR §876.5630
Regulation Name: Peritoneal dialysis system and accessories
Regulatory Class: II
Product Code: 78 FJS
Dated: November 19, 2001
Received: November 19, 2001

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 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:

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" (21 CFR Part 807.97). 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

8. Indications for Use

510(k) Number: K012502
Device Name: Medigroup Catheter Extender/Repair Kit
Indications for Use: This device is intended for use with Flex-Neck™ catheters and Ash Advantage™ catheters in the event one of two situations described below should occur:

1. Extender Application
   In some patients, the external portion of the PD catheter may be too short for them to comfortably use. For example, obese patients may need an extender kit to be able to work with the external part of the catheter. Other patients may require the external end of the catheter to be more centrally located than it normally might be.

2. Repair Application
   If a peritoneal dialysis catheter develops a fracture in the external portion, the catheter must be trimmed to eliminate the fracture. Doing so, by definition, will shorten the catheter and may make it impractical or difficult or even unsuitable for use. Rather than replace the entire catheter, it is desirable to retain the catheter by extending the external part of the catheter with new tubing.

In either situation, this device enables qualified medical staff to extend and/or repair the external part of an existing Flex-Neck catheter or Ash Advantage catheter by adding a 20 cm long tube to the existing and /or remaining catheter tubing.

(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. Segraves

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012502