K974570
P1/1

Premarket Notification - Peritoneal Dialysis Catheter Connector
Medigroup, Inc.

FEB 27 1998

510(k) Summary of Safety and Effectiveness

Device Information

Classification Name: Peritoneal Dialysis Accessories
Common Name: Peritoneal Dialysis Catheter Connector

Predicate Device

This device is substantially equivalent to titanium connectors legally marketed by Accurate Surgical Instruments. Reference 510(k) # K910787.

Device Description & Intended Use

Peritoneal dialysis connectors are used to connect the peritoneal dialysis catheter to the dialysate line. Medigroup intends to market titanium connectors for use with their large diameter, low durometer (Flex Neck™) catheters only. These connectors have the same intended use, general configuration, and materials as titanium connectors marketed by Accurate Surgical Instruments.

Comparison to Predicate Device

	Accurate Surgical Instruments Peritoneal Dialysis Catheter Connector # K910787	Medigroup Peritoneal Dialysis Catheter Connector
Configuration	Two-piece connector	Two-piece connector
Connection Method	Main body with single, rounded barb; cap over the catheter end with screw lock onto main body	Main body with single, rounded barb; cap over the catheter end with screw lock onto main body
Material	Medical grade titanium	Medical grade titanium
Sterilization Method	100% ETO	100% ETO

Testing

Functional testing has been performed to demonstrate mechanical integrity, including connector retention.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 27 1998

Mr. John Navis
President
Medigroup, Inc.
615 Enterprise Street
Aurora, IL 60504-8138

Re: K974570
Titanium Two-Piece Connector
(for Peritoneal Dialysis Catheter)
Dated: December 5, 1997
Received: December 8, 1997
Regulatory Class: II
21 CFR 876.5630/Procode: 78 FKO

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 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,

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

STATEMENT OF INTENDED USE FORM

510(k) #_____

Device Name: Peritoneal Dialysis Catheter Connector

Indications for Use:

Peritoneal dialysis connectors are used to connect the peritoneal dialysis catheter to the dialysate line.

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Robert P Nathing J

(Division **Sign-Off**)
Division of **Reproductive**, Abdominal, ENT,
and Radiological **Devices**
510(k) Number K974570