DEC 0 6 2001

7.1. 510(k) Summary of Safety and Effectiveness

7.1.1 Basic Data

Date Prepared:	September 6, 2001
Company:	MEDIGROUP, Inc
Contact:	John A. Navis, President
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7.1.2 Device Information:

Classification Name:	Peritoneal Catheter Accessory
Common Name:	Catheter Implantation Device

7.1.3 Predicate Device

This device (Key Tube™) is an adaptation (not replacement) for an existing tool, Cuff Implantor®, currently produced by Medigroup and included in two of its Y-TEC® kits, VP-112 and VP-210, 510(k)883303A and adapted in April 7, 1993 letter to FDA. An early prototype Key Tube version was designed and used during the Ash Advantage™ clinical trials [510(k)991042].

7.1.4 Ash Advantage™ catheter clinical trials were conducted in three dialysis centers. A total of fourteen catheters were implanted in thirteen patients via the peritoneoscopic or laprascopic method (doctor's choice). All implanting doctors used the prototype version of the Key Tube™ to implant the Ash Advantage™ catheter.

Clinical results were that all catheters were successfully implanted; the Key Tube™ functioned as designed. That is, the T junction of the Ash Advantage™ was against the parietal peritoneum; the distal cuff was within the rectus sheath; incision of the rectus sheath was avoided.

7.1.5 Device Description and Intended Use

Stainless steel, quasi tubular (U shape) device, approximately 200 mm long and 8.0 mm diameter.

It is designed to be used to implant the Ash Advantage catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 6 2001

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

Re: K013017
Trade/Device Name: Key Tube™ (KT-2580)
Regulation Number: 21 CFR §876.5630
Regulation Name: Peritoneal dialysis system and accessories
Regulatory Class: II
Product Code: 78 FJS
Dated: September 6, 2001
Received: September 7, 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

510(k) Number: K013017

Device Name: Medigroup Key Tube™

Indications for Use: The Key Tube is designed to be used to implant the Ash Advantage™ catheter. No usage change from original Ash Advantage catheter 510(k) 991042.

(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. Seaman

[redacted]

510(k) Number K013017