July 27, 2018

Covidien, llc
Carol Ming
Sr. Regulatory Affairs Specialist
15 Hampshire Street
Mansfield, MA 02048

Re: K180485
Trade/Device Name: Argyle™ Peritoneal Dialysis Catheter and Kits; Argyle™ Presternal Peritoneal Dialysis Catheter and Kits; Argyle™ Peritoneal Dialysis Accessory Two Part Titanium Luer Adapter; Argyle™ Adult Peritoneal Dialysis Accessory Titanium Catheter Extender
Regulation Number: 21 CFR§ 876.5630
Regulation Name: Peritoneal Dialysis System and Accessories
Regulatory Class: II
Product Code: FJS, FKO
Dated: June 26, 2018
Received: June 27, 2018

Dear Carol Ming:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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/tray. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joyce M. Whang -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180485

Device Name
Argyle(TM) Peritoneal Dialysis Catheter and Kits; Argyle(TM) Presternal Peritoneal Dialysis Catheter and Kits; Argyle(TM) Peritoneal Dialysis Accessory Two Part Titanium Luer Adapter; Argyle(TM) Adult Peritoneal Dialysis Accessory Titanium Catheter Extender

Indications for Use *(Describe)*

Argyle(TM) Peritoneal Dialysis Catheter and Kits:
The peritoneal catheter is indicated for acute and chronic peritoneal dialysis.
The peritoneal dialysis catheter may be inserted using open, laparoscopic or percutaneous surgical techniques.

Argyle (TM) Presternal Peritoneal Catheter and Kits:
The presternal peritoneal catheter is indicated for acute and chronic peritoneal dialysis.
The Peritoneal Dialysis catheter may be inserted using open, laparoscopic or percutaneous surgical techniques.

Argyle(TM) Peritoneal Dialysis Accessory Two Part Titanium Luer Adapter:
The Two Part Titanium Luer Adapter is indicated for acute and chronic peritoneal dialysis, to be used with the Argyle(TM) Peritoneal Dialysis Catheter and the Argyle(TM) Presternal Peritoneal Dialysis Catheter.
The Two Part Titanium Luer Adapter is designed to provide a permanent threaded closure when used with a standard continuous ambulatory peritoneal dialysis (CAPD) transfer set.

Argyle(TM) Adult Peritoneal Dialysis Accessory Titanium Catheter Extender
The Titanium Catheter Extender is indicated for acute and chronic peritoneal dialysis, to be used with the Argyle(TM) Peritoneal Dialysis Catheter and the Argyle(TM) Presternal Peritoneal Dialysis Catheter.
The adult catheter extender is used to extend a catheter by connecting two portions of the peritoneal catheter tubing.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5. 510(k) Summary

5.1 Submitter

Covidien, llc
15 Hampshire Street
Mansfield, MA 02048

Contact Person: Carol Ming
Sr. Regulatory Affairs Specialist
Phone: 508.452.1443

Date Prepared: July 27, 2018

5.2 Device Names and Classifications:

Trade Name:	Argyle™ Peritoneal Dialysis Catheter and Kits
Common Name:	Peritoneal catheter (PD catheter)
Regulation Number:	21 CFR 876.5630
Regulation Name:	Peritoneal Dialysis System and Accessories
Product Code:	FJS
Classification:	Class II

Trade Name:	Argyle™ Presternal Peritoneal Dialysis Catheter and Kits
Common Name:	Peritoneal catheter (PD catheter)
Regulation Number:	21 CFR 876.5630
Regulation Name:	Peritoneal Dialysis System and Accessories
Product Code:	FJS
Classification:	Class II

Trade Name:	Argyle™ Peritoneal Dialysis Accessory Two Part Titanium Luer Adapter
Common Name:	Titanium Connector (2 part)
Regulation Number:	21 CFR 876.5630
Regulation Name:	Peritoneal Dialysis System and Accessories
Product Code:	FKO
Classification:	Class II

Trade Name:	Argyle™ Adult Peritoneal Dialysis Accessory Titanium Catheter Extender
Common Name:	Titanium catheter extender
Regulation Number:	21 CFR 876.5630
Regulation Name:	Peritoneal Dialysis System and Accessories
Product Code:	FJS
Classification:	Class II

5.3 Predicate Device

Flex-Neck® ExxTended™ PD Catheter & Accessories, FJS, K071167

5.4 Device Description

The Argyle™ Peritoneal Dialysis Catheter products are single lumen catheters for acute and chronic peritoneal dialysis to allow consistent bi-directional flow of dialysate into and out of the abdominal cavity. One or more cuffs are bonded on to the catheter tubing, which allows for tissue ingrowth to maintain placement of the catheter. All catheters are made of translucent silicone rubber tubing containing a radiopaque stripe, with felt cuffs available to provide catheter stabilization by virtue of tissue in-growth.

The Argyle™ peritoneal dialysis catheter comes in a variety of lengths and cuff configurations including straight, curled, and Swan Neck catheter styles. The Argyle™ peritoneal dialysis catheter kit contains the basic items needed to insert a peritoneal catheter: a straight or Swan Neck Tenckhoff or Curl Cath catheter with single or double cuff (specified at time of order), a 16 Fr/Ch pull-apart introducer, an 18 G introducer needle, a 12 mL syringe, a J/straight guidewire, tunneling stylet, #11 scalpel, gauze sponges, Beta-Cap™ adapter, cap, clamp, and instructions.

The Argyle™ presternal peritoneal dialysis catheters include the curl catheter and Swan Neck catheter styles. The curl catheter segment contains a felt cuff. The Swan Neck Presternal catheter is a segment of catheter tubing with a Swan Neck bend and two cuffs. It is connected by a double-barbed connector to the intraperitoneal segment of the curl catheter. The Argyle™ presternal peritoneal dialysis catheter kit contains the basic items needed to insert a peritoneal catheter: a 16 Fr/Ch pull-apart introducer, an 18 G introducer needle, a 12 mL syringe, a J/straight guidewire, tunneling stylet, #11 scalpel, gauze sponges, Beta-Cap™ adapter, cap, clamp, titanium connector, and instructions.

The titanium adapter is a two-piece luer-lock system with a barbed end and a threaded cover. The adapter is designed to provide a permanent threaded closure when used with a standard CAPD transfer set.

The adult catheter extender is double barbed and made of titanium. The adult catheter extender is used to extend a catheter by connecting two portions of the peritoneal catheter tubing.

5.5 Indications for Use

Model Names/Types	Indications
Peritoneal Dialysis Catheter and Kits	The peritoneal catheter is indicated for acute and chronic peritoneal dialysis. The peritoneal dialysis catheter may be inserted using open, laparoscopic or percutaneous surgical techniques.

Model Names/Types	Indications
Presternal Peritoneal Catheters and Kit	The presternal peritoneal catheter is indicated for acute and chronic peritoneal dialysis. The Peritoneal Dialysis catheter may be inserted using open, laparoscopic or percutaneous surgical techniques.
Peritoneal Dialysis Accessory Two Part Titanium Luer Adapter	The Two Part Titanium Luer Adapter is indicated for acute and chronic peritoneal dialysis, to be used with the Argyle(TM) Peritoneal Dialysis Catheter and the Argyle(TM) Presternal Peritoneal Dialysis Catheter. The Two Part Titanium Luer Adapter is designed to provide a permanent threaded closure when used with a standard continuous ambulatory peritoneal dialysis (CAPD) transfer set.
Adult Peritoneal Dialysis Accessory Titanium Catheter Extender	The Titanium Catheter Extender is indicated for acute and chronic peritoneal dialysis, to be used with the Argyle(TM) Peritoneal Dialysis Catheter and the Argyle(TM) Presternal Peritoneal Dialysis Catheter. The adult catheter extender is used to extend a catheter by connecting two portions of the peritoneal catheter tubing.

5.6 Comparison to Predicate Device

This submission addresses the Peritoneal Dialysis Catheter and Kits and the Peritoneal Dialysis Presternal Catheter and Kits. Also included in the submission are accessories used with these devices, the Peritoneal Dialysis Accessory Two Part Titanium Luer Adapter and the Adult Peritoneal Dialysis Accessory Titanium Catheter Extender. The new information presented in this submission is for the addition of the laparoscopic placement to the indications for use in the IFUs for the PD catheters and kits. In addition, the MR status of the devices in this submission is being added to the IFUs for the devices.

The Merit device, the Flex-Neck® ExxTended™ PD Catheter & Accessories, is being used as a predicate device as the IFU for the Flex-Neck® ExxTended™ PD Catheter & Accessories includes the option for laparoscopic placement in the indications for use statement. The updates to the IFUs did not entail any design changes to the subject devices.

The predicate and proposed PD catheter devices and accessories are the same devices and accessories, as this submission addresses only adding an indication to the Instructions for Use (IFU) for inserting the peritoneal dialysis catheters through a port, laparoscopically. The IFUs for the devices are also being updated to indicate the devices as having MR Safe or MR Conditional status.

The PD catheters and accessories have an equivalent design, materials and principles of operation and technology when compared to the predicate device. The indications for use of the PD catheters is being updated to include an indication for laparoscopic placement. The MR Safe or MR Conditional status of the devices and accessories is also being included in the updated IFUs for these products.

- Intended Use: Peritoneal Dialysis catheters are intended to provide access for acute and chronic peritoneal dialysis. The catheter functions as a means to deliver and extract peritoneal dialysis solution in and out of the patient's peritoneal cavity.
- Materials: The materials of the proposed PD Catheters and accessories are the same as the predicate devices.
- Principles of Operation and Technology: The technology of the proposed devices and accessories and the predicate device is the same.
- Performance: The performance of the proposed PD Catheters and accessories remains unchanged and continues to meet the performance specifications.

5.7 Performance Data

Biocompatibility:

The biocompatibility evaluation was conducted for an externally communicating, tissue/bone/dentin, and permanent duration (>30 days) device. The series of testing was conducted utilizing the PD Catheter and using Good Laboratory Practice (GLP). The testing procedures are based on the requirements of ISO 10993-1 and the following series of testing was conducted utilizing the Argyle Peritoneal Dialysis Catheter:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Subchronic Toxicity
- Genotoxicity
    - AMES
    - Mouse Lymphoma
    - Mouse Micronucleaus
- Implantation
- Chronic Toxicity

The results of the biocompatibility tests conducted on the PD catheter meet the ISO 10993 requirements and have been deemed acceptable.

Performance Testing:

Design verification testing was performed with the proposed device to support the indication expansion for laparoscopic insertion, including evaluation of insertion through a 7mm/8mm port (trocar).

The updates being made to the IFUs to include insertion through a port under laparoscopic visualization was subjected to validation testing by clinicians. Finally, test results are included to verify that the catheters and accessories are MRI Safe or MR Conditional. The IFUs for the catheters and accessories have been updated to include that information.

All performance testing met acceptance criteria and supports the determination of substantial equivalence to the predicate devices and accessories.

Performance Testing (Animal)
None Provided

Performance Testing (Clinical)

None Provided

5.8 Conclusions

Medtronic has demonstrated that the Peritoneal Dialysis (PD) Catheters are substantially equivalent to the predicate device and supports the update to the indications for use to include the laparoscopic placement indication.
In addition, Argyle™ peritoneal dialysis catheter's manufactured with silicone tubing and radiopaque stripe strip are considered to be MR Safe, while the Argyle™ presternal peritoneal dialysis catheters plus titanium connectors are considered MR Conditional.