January 14, 2022

Covidien, llc
Carol Ming
Pr. Regulatory Affairs Specialist
15 Hampshire Street
Mansfield, Massachusetts 02048

Re: K213602
Trade/Device Name: Ritus™ Peritoneal Dialysis Catheter Tunneling Tool Kit
Regulation Number: 21 CFR 876.5630
Regulation Name: Peritoneal dialysis system and accessories
Regulatory Class: II
Product Code: FJS
Dated: November 11, 2021
Received: November 15, 2021

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. 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Glenn B. Bell, Ph.D.
Director
THT3A1: Renal, Gastrointestinal,
Obesity and Transplantation Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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)*
K213602

Device Name
Ritus Peritoneal Dialysis Catheter Tunneling Tool Kit

Indications for Use *(Describe)*
The Ritus™ tunneling tool kit is used to both create a tunnel tract through subcutaneous tissue and seal the end of the catheter. This allows the external portion of the Covidien™ peritoneal dialysis catheter to be temporarily buried in advance of dialysis for patients that are candidates for delayed peritoneal dialysis treatment.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5. 510(k) Summary

Medtronic

5.1 Submitter

Covidien, llc
15 Hampshire Street
Mansfield, MA 02048

Contact Person: Carol Ming
Pr. Regulatory Affairs Specialist
Phone: 508.452.1443
Email: carol.s.ming@medtronic.com

Date Prepared: November 11, 2021

5.2 Device Names and Classifications:

Trade Name:	Ritus™ Peritoneal Dialysis Catheter Tunneling Tool Kit
Common Name:	Peritoneal Dialysis Accessories
Regulation Number:	21 CFR 876.5630
Product Code:	FJS
Classification:	Class II

5.3 Predicate Device

Embedding® Tool, FJS, K060897

5.4 Device Description

The Ritus™ tunneling tool kit comes with a separate tunneling device and plug. This kit is designed to create a subcutaneous tunnel to temporarily bury the external portion of the peritoneal dialysis catheter within the abdominal, subcutaneous tissue in advance of needing dialysis.

The tunneling device is made of stainless steel with a rigid plastic handle on the proximal end. There is an angled tip with a removable plastic cap. Functioning as a dilator, the tunneling device separates the tissue to create a tunnel tract, then is used to pull the catheter through the tunnel to desired exit site.

The titanium catheter plug is designed to seal the end of the catheter for the length of time that the catheter is buried within the subcutaneous tissue.

5.5 Indications for Use

Model Names/Types	Indications
Ritus™ Peritoneal Dialysis Catheter Tunneling Tool Kit	The Ritus™ tunneling tool kit is used to both create a tunnel tract through subcutaneous tissue and seal the end of the catheter. This allows the external portion of the Covidien™ peritoneal dialysis catheter to be temporarily buried in advance of dialysis for patients that are candidates for delayed peritoneal dialysis treatment.

5.6 Comparison to Predicate Device

The technological characteristics, design and performance of the Tunneling Tool Kit are consistent with those of the predicate devices.

- Intended Use: The intended use of the proposed device and the predicate device is the same.
- Materials: Both the proposed device and the predicate device have titanium catheter plugs. The tunneling device for the Tunneling Tool Kit has a similar design as the predicate, but the proposed tunneling device's tip and shaft is made of stainless steel while the predicate is made of rigid polyvinyl compound (RPVC).
- Principles of Operation and Technology: The technology of the proposed device and the predicate device is the same.
- Performance: The performance of the proposed device and the predicate device is the same.

5.7 Performance Data

Materials / Biocompatibility:

Biocompatibility testing was conducted based on the requirements of ISO 10993-1:2018 and using Good Laboratory Practice (GLP). The results of the biocompatibility tests conducted show the Ritus™ Peritoneal Dialysis Catheter Tunneling Tool Kit meets the ISO 10993 requirements and have been deemed acceptable.

Performance Testing:

Design verification testing was performed with the proposed device and is summarized in order to establish the equivalent performance with the predicate. All performance testing met acceptance criteria and supports the determination of substantial equivalence to the predicate devices.

5.8 Conclusions

The indications for use and intended use of the Ritus™ Peritoneal Catheter Tunneling Tool Kit is substantially equivalent to that of the predicate device. Additionally, Covidien has demonstrated that the device works as designed and intended.