January 17, 2020

Covidien, LLC
Carol Ming
Principal Regulatory Affairs Specialist
15 Hampshire Street
Mansfield, MA 02048

Re: K192302
Trade/Device Name: Mahurkar Acute Single Lumen Catheter,
Mahurkar Acute Dual Lumen Catheter,
Mahurkar Acute Triple Lumen Catheter,
Mahurkar Acute High Pressure Triple Lumen Catheter
Regulation Number: 21 CFR 876.5540
Regulation Name: Blood Access Device and Accessories
Regulatory Class: II
Product Code: MPB, NIE
Dated: December 17, 2019
Received: December 19, 2019

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/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.

In addition, we have determined that your device kit contains lidocaine and ChloraPrep, which are subject to regulation as drugs.

Our substantially equivalent determination does not apply to the drug components of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug components. For information on applicable Agency requirements for marketing these drugs, we suggest you contact:

Director, Division of Drug Labeling Compliance
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

This letter will allow you to begin marketing your device as described in your Section 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.

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,

Carolyn Y. Neuland, Ph.D.
Assistant Director
DHT3A: Division of Renal,
Gastrointestinal, Obesity
and Transplant 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)*
K192302

Device Name
Mahurkar(TM) Acute Single Lumen Catheter / Mahurkar(TM) Acute Dual Lumen Catheter /
Mahurkar(TM) Acute Triple Lumen Catheter / Mahurkar(TM) Acute High Pressure Triple Lumen Catheter

Indications for Use *(Describe)*
The Mahurkar(TM) Acute Single Lumen Catheters provides temporary access for acute hemodialysis. The flexible tubing permits percutaneous insertion into subclavian, jugular, and femoral veins.

The Mahurkar(TM) Acute Dual Lumen Catheters are intended for short-term central venous access for hemodialysis, apheresis, and infusion.

The Mahurkar(TM) Acute Triple Lumen Catheters are intended for short-term central venous access for hemodialysis, apheresis, and infusion.

The Mahurkar(TM) Acute High Pressure Triple Lumen Catheters are intended for short term central venous access for hemodialysis, apheresis, infusion, central venous pressure monitoring and pressure injection of contrast media. The maximum recommended infusion rate is 5 mL/sec for power injection of contrast media.

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.

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Office of Chief Information Officer
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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."

510(k) Summary

5.1 Submitter Information

Company: Covidien, llc
15 Hampshire Street
Mansfield, MA 02048

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

Date Prepared: October 3, 2019

5.2 Device Names and Classifications:

Trade Name: Mahurkar™ Acute Single Lumen Catheter
Common Name: Non-Implanted Hemodialysis Catheter
Regulation Number: 21 CFR 876.5540
Regulation Name: Blood Access Device and Accessories
Product Code: MPB
Classification: Class II

Trade Name: Mahurkar™ Acute Dual Lumen Catheter
Common Name: Non-Implanted Hemodialysis Catheter
Regulation Number: 21 CFR 876.5540
Regulation Name: Blood Access Device and Accessories
Product Code: MPB
Classification: Class II

Trade Name: Mahurkar™ Acute Triple Lumen Catheter
Common Name: Non-Implanted Triple Lumen Hemodialysis Catheter
Regulation Number: 21 CFR 876.5540
Regulation Name: Blood Access Device and Accessories
Product Code: NIE
Classification: Class II

Trade Name: Mahurkar™ Acute High Pressure Triple Lumen Catheter
Common Name: Non-Implanted Triple Lumen Hemodialysis Catheter
Regulation Number: 21 CFR 876.5540
Regulation Name: Blood Access Device and Accessories
Product Code: NIE
Classification: Class II

5.3 Predicate Device

Primary Predicate Devices:

K896252 Argyle™ Single Lumen Catheter

K943349 Mahurkar™ Dual Lumen Catheter

K030209 Mahurkar™ Dual Lumen High Flow Catheter (Q-PLUS)

K020089 Mahurkar™ Triple Lumen Catheter

K102605 Mahurkar™ Triple Lumen High Pressure Dialysis Catheter

Reference Device:

K120674 Mahurkar™ Elite Dual and Triple Lumen Catheters (MPB, NIE)

5.4 Device Description

The Mahurkar™ Acute Single Lumen Catheter is a radiopaque, polyurethane tube that features a single-lumen design on the proximal end. A rotatable suture wing, for securing the catheter to the patient, is attached to the hub and five outflow holes are arranged in a spiral near the tapered tip. The single lumen catheter is available in 8.0 Fr outer diameter and in implant lengths 15 cm and 19.5 cm. An optional, disposable Y-adapter can be used to convert the single extension to a dual.

The Mahurkar™ Acute Dual Lumen Catheter is a radiopaque, polyurethane tube that features a two-lumen design on the proximal end. The color-coded adapters on each lumen indicate arterial and venous flow. The adapters are connected to extension tubes which are available in curved or straight configurations. The extension tubes are connected, by a hub, to a dual lumen shaft that is available in pre-curved and straight configurations. The shaft extends to side slots near the distal tip. The dual lumen catheter is available in 8.0 Fr, 10.0 Fr, 11.5 Fr, or 13.5 Fr outer diameters and a variety of implant lengths ranging from 9 cm to 24 cm. It is offered as a single device or as convenience kits.

The Mahurkar™ Acute Triple Lumen Catheter and the Mahurkar™ Acute High Pressure Triple Lumen Catheter are radiopaque, polyurethane tubes that features a three-lumen design on the proximal end. The color-coded adapters on each lumen indicate arterial flow, venous flow, and medial infusion. The adapters are connected to extension tubes which are available in curved or straight configurations. The extension tubes are connected, by a hub, to a triple lumen shaft that extends to side slots near the distal tip. The triple lumen catheter is available in 12 Fr outer diameter and a variety of implant lengths ranging from 13 cm to 24 cm. They are offered as a single device or as convenience kits.

5.5 Indications for Use

The Mahurkar™ Acute Single Lumen Catheters provides temporary access for acute hemodialysis. The flexible tubing permits percutaneous insertion into subclavian, jugular, and femoral veins.

The Mahurkar™ Acute Dual Lumen Catheters are intended for short-term central venous access for hemodialysis, apheresis, and infusion.

The Mahurkar™ Acute Triple Lumen Catheters are intended for short-term central venous access for hemodialysis, apheresis, and infusion.

The Mahurkar™ Acute High Pressure Triple Lumen Catheters are intended for short term central venous access for hemodialysis, apheresis, infusion, central venous pressure monitoring and pressure injection of contrast media. The maximum recommended infusion rate is 5 mL/sec for power injection of contrast media.

5.6 Comparison to Predicate Device

This submission addresses the Mahurkar™ Acute Single, Dual and Triple Lumen Catheters, kits and trays. The new information presented in this submission includes changes to the Priming Volume printed on the label, printed on the Instructions for Use and printed on the subject devices. In addition, the Mahurkar™ Acute Triple Lumen Catheters' and Mahurkar™ Acute High Pressure Triple Lumen Catheters' medial lumen static flowrate tables will be changed from average flow rates to minimum flowrates to align with ISO 10555-1.

The previously cleared Mahurkar™ Acute Single, Dual and Triple Lumen Catheters are being used as predicate devices. The predicate devices and the proposed catheters are the same devices, as this submission addresses only changing the printed priming volume on the subject devices. No material, design or principle of operation changes have been made to the Mahurkar™ Acute Catheters, Kits and Trays for the purposes of this submission.

The Mahurkar™ Acute Single, Dual and Triple Lumen Catheters, kits and trays have equivalent design, materials and principles of operation and technology when compared to the predicate device.

- Design: The design of the proposed Mahurkar™ Acute Single, Dual and Triple Lumen Catheters, kits and trays are the same as the predicate device.
- Materials: The materials of the proposed Mahurkar™ Acute Single, Dual and Triple Lumen Catheters, kits and trays are the same as the predicate device.
- Principles of Operation and Technology: The technology of the proposed Mahurkar™ Acute Single, Dual and Triple Lumen Catheters, kits and trays are the same as the predicate device.

5.7 Performance Data

Biocompatibility:

There were no changes to materials for this submission. Previously, biocompatibility evaluation was conducted for an externally communicating, circulating blood and prolonged exposure (<30 days) device. The series of testing was conducted utilizing the Mahurkar™ Acute Catheters 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 Mahurkar™ Acute Catheters.

Tests Performed:

- Cytotoxicity - MEM Elution Test
- Sensitization - Guinea Pig Maximization Test
- Irritation – Primary Skin Irritation
- Intracutaneous Toxicity Test
- Acute Systemic Injection Test
- Subchronic Toxicity
- Genotoxicity
    - AMES Test for Mutagenicity
- 30-Day Muscle Implantation Test
- Hemolysis Test – Saline Extract Method
- USP Rabbit Pyrogen Test

The results of the biocompatibility tests conducted on the Mahurkar™ Acute Catheters meet the ISO 10993 requirements and have been deemed acceptable.

Performance Testing:

Engineering testing analysis were performed and are summarized in order to establish the equivalence with the predicate devices. The test regimen evaluated the devices for priming volumes and cleaning agent compatibility. Additionally, the triple lumen catheter has been evaluated for static flow rates of the medial lumens.

Performance Testing (Animal)

None Provided

Performance Testing (Clinical)

None Provided

5.8 Conclusions

Medtronic has demonstrated that the Mahurkar™ Acute Single, Dual and Triple Lumen Catheters, kits and trays are substantially equivalent to the predicate device and support the update to the priming volumes printed on the label, IFU and device and the static flow rates of the triple lumen's medial lumen.