DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 6, 2017

Cook Incorporated
Steven Lawrie, MS, MA, RAC
Regulatory Affairs Manager
750 Daniels Way
Bloomington, IN 47404

Re: K161504
Trade/Device Name: Cook Turbo-Flo HD Acute Hemodialysis Catheter Set/Tray
Regulation Number: 21 CFR§ 876.5540
Regulation Name: Blood Access Device and Accessories
Regulatory Class: II
Product Code: MPB
Dated: December 7, 2016
Received: December 8, 2016

Dear Steven Lawrie:

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. 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); 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.

In addition, we have determined that your device kit contains Lidocaine which is subject to regulation as a drug.

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161504

Device Name
Cook Turbo-Flo® HD Acute Hemodialysis Catheter Set/Tray

Indications for Use *(Describe)*
The Cook Turbo-Flo® HD Acute Hemodialysis Catheter Set/Tray is intended for acute hemodialysis, apheresis and hemofiltration via percutaneous insertion into the subclavian, jugular, or femoral veins. The device is a short-term use catheter (less than 30 days).

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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Food and Drug Administration
Office of Chief Information Officer
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510(k) SUMMARY

Cook Turbo-Flo® HD Acute Hemodialysis Catheter Set/Tray
21 CFR §880.5570
Date Prepared: 6 January 2017

Submitted By:	
Applicant:	Cook Incorporated
Contact:	Steven Lawrie
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact Phone Number:	(812) 335-3575 x104518
Contact Fax Number:	(812) 332-0281
Device Information:	
Trade Name:	**Cook Turbo-Flo® HD Acute Hemodialysis Catheter Set/Tray**
Common Name:	Blood access device and accessories
Classification Name:	Catheter, Hemodialysis, Non-implanted
Regulation:	21 CFR §876.5540
Product Code:	MPB

Predicate Device:

- K122091 – Cook Turbo-Flo® HD Acute Hemodialysis Catheter Set/Tray

Device Description:

The Cook Turbo-Flo® HD Acute Hemodialysis Catheter Set/Tray is a short-term, 12 Fr, radiopaque polyurethane central venous catheter with two independent, non-communicating lumens. Lengths of 15, 20, and 25 cm are available based on the anatomical needs of the patient.

Intended Use:

The Cook Turbo-Flo HD Acute Hemodialysis Catheter Set/Tray is intended for acute hemodialysis, apheresis and hemofiltration via percutaneous insertion into the subclavian, jugular, or femoral veins. The device is a short-term use catheter (less than 30 days).

Comparison to Predicates:

The Cook Turbo-Flo® HD Acute Hemodialysis Catheter Set/Tray is substantially equivalent to the predicate device, the Cook Turbo-Flo® HD Acute Hemodialysis Catheter Set/Tray (K122091) in that these devices have identical intended use, catheter materials, and technological characteristics. The only difference as compared to the

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predicate is the removal of the hydrophilic coating from the external surface of the catheter shaft.

Technological Characteristics:

The following tests have been conducted to ensure reliable design and performance under the specified design requirements:

- Validation testing – When tested in an animal model that simulates clinical use, the rating scale of the following performance parameters should be "adequate" or "good" in a three-point scale: preparation, introduction, pushability, trackability, flexibility, radiopacity, blood draw, infusion, interaction, withdrawal, and inspection. The pre-determined acceptance criterion was met.
- Biocompatibility testing – The results of testing (cytotoxicity, direct and indirect hemolysis, complement activation, partial thromboplastin time, and *in vitro* hemocompatibility) indicate that the modification to the subject device does not impact its biocompatibility.

Conclusion:

After conducting appropriate design control activities and performing an appropriate validation test, it is concluded that the proposed Cook Turbo-Flo® HD Acute Hemodialysis Catheter Set/Tray has met the design input requirements based on the intended use and that the modification to the device does not raise new questions of safety or effectiveness as compared to the predicate device. Therefore, the Cook Turbo-Flo® HD Acute Hemodialysis Catheter Set/Tray has been demonstrated to be substantially equivalent to the predicate device, the Cook Turbo-Flo® HD Acute Hemodialysis Catheter Set/Tray (K122091).