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

September 2, 2016

Cook Incorporated
Mr. Chad Schulenburg
Regulatory Affairs Specialist
750 Daniels Way, P.O. Box 489
Bloomington, IN 47404

Re: K160593
Trade/Device Name: Indy OTW Vascular Retriever
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: MMX
Dated: July 29, 2016
Received: August 1, 2016

Dear Mr. Schulenburg:

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. 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.

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,

Brian D. Pullin -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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)*
K160593

Device Name
Indy OTW™ Vascular Retriever

Indications for Use *(Describe)*
The Indy OTW Vascular Retriever is intended to snare a foreign body and withdraw it to a peripheral vascular location.

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."

COOK INCORPORATED
750 DANIELS WAY
BLOOMINGTON, IN 47404 USA
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

510(k) SUMMARY
As required by 21 CFR §807.92
Date Prepared: July 29, 2016

I. SUBMITTER

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Cook Incorporated
Contact:	Chad Schulenburg
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact Phone Number:	(812) 335-3575 ext. 104073
Contact Fax Number:	(812) 332-0281

II. DEVICE

Trade Name:	Indy OTW™ Vascular Retriever
Common Name:	Percutaneous Retrieval Device
Classification Name:	Embolectomy Catheter
Regulation/Class:	21 CFR §870.5150/Class II
Product Code	MMX

III. PREDICATE DEVICE

The device subject of this submission is considered substantially equivalent to the predicate device, the 4-Loop Vascular Retriever Snare (K112185).

IV. DEVICE DESCRIPTION

The Indy OTW™ Vascular Retriever consists of a 4-loop nitinol wire snare attached to an inner catheter (which is attached proximally to a metal cannula) and includes an outer Flexor sheath. The device is compatible with a 0.035 inch wire guide for over-the-wire introduction. The Flexor sheath has a radiopaque band incorporated within the sheath material to identify the location of the sheath's distal tip.

V. INDICATIONS FOR USE

The Indy OTW™ Vascular Retriever is intended to snare a foreign body and withdraw it to a peripheral vascular location.

COOK INCORPORATED
750 DANIELS WAY
BLOOMINGTON, IN 47404 USA
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Indy OTW™ Vascular Retriever and the predicate device, the 4-Loop Vascular Retriever Snare (K112185), are substantially equivalent in that these devices have the same intended use and similar technological characteristics.

Table 1: Comparison Table

	PREDICATE DEVICE	SUBJECT DEVICE
	4-Loop Vascular Retriever Snare (K112185)	**Indy OTW Vascular Retriever (Subject of this Submission)**
Regulation Number	870.5150	Identical
Product Code	MMX	Identical
Classification Name	Embolectomy Catheter	Identical
Class	II	Identical
Intended Use	Intended for use in the cardiovascular system to manipulate and retrieve foreign objects, including, but not limited to, wire guides, coils, balloons, catheters, and filters.	Intended to snare a foreign body and withdraw it to a peripheral vascular location.
Model Number Prefix	VRS	INDY
Snare Sub-Assembly	5 Nitinol strands / 2 Tantalum strands	5 Nitinol strands / 2 Platinum strands
Snare Loops	4	Identical
Inner Catheter	Radiopaque Tetrafluoroethylene (TFE)	Nylon radiopaque tubing
Catheter Length (cm)	90	55, 100
Sheath	Nylon	Flexor sheath: Nylon outer layer, Embedded steel coil, PTFE inner liner
Outer Sheath Size (Fr)	10.0	8.0
Connector Cap	Nylon	Identical

COOK INCORPORATED
750 DANIELS WAY
BLOOMINGTON, IN 47404 USA
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

	PREDICATE DEVICE	SUBJECT DEVICE
	4-Loop Vascular Retriever Snare (K112185)	**Indy OTW Vascular Retriever (Subject of this Submission)**
Side Arm Assembly	Tuohy-Borst adapter material: Polycarbonate Male luer cap with strap material: High density polyethylene/polyvinyl chloride	Identical
Wire Guide Compatibility (diameter in inches)	N/A	0.035
Packaging	PETG tray PET-PE / Tyvek pouch	Wire guide holder PET-PE / Tyvek pouch
Sterilization Method	EtO	Identical
SAL	10^{-6}	Identical
Shelf Life	3 years	Identical

The minor differences in dimensions, materials, and technology as compared to the predicate device were appropriately assessed and do not present any new questions of safety and/or effectiveness. The following devices were referenced to provide additional support: Flexor® Introducers (K142829), SeQure™ Snare System (K102484), Roadrunner® Uniglide® Hydrophilic Wire Guide (K110009), Approach® Pro ST Micro Wire Guides (K110163) and the Coda® Low Profile Balloon Catheter (K150970). Based on the comparison of the design, intended use, materials, fundamental technology, and principle of operation, the subject device is considered to be substantially equivalent to the currently marketed predicate device.

VII. PERFORMANCE DATA

Biocompatibility testing and performance testing were conducted to ensure that the Indy OTW™ Vascular Retriever will not elicit an adverse biological response in patients and will reliably perform as intended.

- Biocompatibility Testing – Cytotoxicity, Sensitization, Intracutaneous Reactivity, Acute Systematic Toxicity, Hemocompatibility, and Pyrogenicity tests were performed. All test results were acceptable and demonstrate that the device is biocompatible.

COOK INCORPORATED
750 DANIELS WAY
BLOOMINGTON, IN 47404 USA
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

- Tensile Strength Testing – Peak load values of joints between device components were in accordance with the predetermined acceptance criteria demonstrating that the joints have sufficient strength to remain intact during use.
- Simulated Use Testing – The Indy OTW™ Vascular Retriever was capable of snaring and removing wire guides and catheter fragments or snaring and repositioning wire guides and catheters within an anatomical model in accordance with the instructions for use. The predetermined acceptance criteria were met.
- Liquid Leak Pressure Testing –The sheath hub, Touhy-Borst, and catheter hub did not leak water while pressurized. The predetermined acceptance criterion was met.
- Structural Integrity Testing –The device maintained structural integrity under the conditions of the study. The predetermined acceptance criteria were met.
- Radiopacity Testing – The catheter tip, sheath tip, and wire loops are visible under standard fluoroscopy. The predetermined acceptance criterion was met.
- Immersion Corrosion Testing – No evidence of corrosion was observed. The predetermined acceptance criterion was met.

VIII. CONCLUSIONS

The results of the testing provide reasonable assurance that the subject device has been designed such that it will function as intended to snare a foreign body and withdraw it to a peripheral vascular location. The subject device does not raise new questions of safety or effectiveness as compared to the predicate device. This supports a determination of substantial equivalence of the subject device to the predicate device.