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

July 27, 2017

Cook Incorporated
Johnathan Liu
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, Indiana 47404

Re: K163031
Trade/Device Name: Bunegin-Albin Air Aspiration Set
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: DXE
Dated: June 24, 2017
Received: June 27, 2017

Dear Johnathan Liu:

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,

Kenneth J. Cavanaugh -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)*

K163031

Device Name
Bunegin-Albin Air Aspiration Set

Indications for Use *(Describe)*
The Bunegin-Albin Air Aspiration Set is intended to aspirate venous air emboli.

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.

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2.0 510(k) SUMMARY

K163031
Bunegin-Albin Air Aspiration Set
21 CFR §870.5150
Date Prepared: July 25, 2017

Submitted By:

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Cook Incorporated
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact:	Johnathan Liu
Email:	regsubmissions@cookmedical.com
Contact Phone Number:	(812) 335-3575 x104509
Contact Fax Number:	(812) 332-0281

Device Information:

Trade Name:	**Bunegin-Albin Air Aspiration Set**
Common Name:	Catheter, Embolectomy
Classification Name:	Embolectomy Catheter
Regulation:	21 CFR §870.5150
Product Code:	DXE
Device Class:	II
Classification Panel:	Cardiovascular

Predicate Device:

The Bunegin-Albin Air Aspiration Set is substantially equivalent to the following device: the Export Advance™ Aspiration Catheter (K130536, Medtronic Inc.) cleared on July 16, 2013.

Device Description:

The Bunegin-Albin Air Aspiration Set is comprised of an air aspiration catheter, wire guide, entry access needle, dilator, syringe, stopcock, and scalpel. The air aspiration catheter is manufactured from radiopaque extruded polyethylene tubing and is designed

with a pre-molded winged fitting. The catheter is 5.8 French in size with an endhole diameter of 0.035 inches. The wire guide is manufactured from stainless steel coils, a safety wire, and a mandril wire. The access needle is manufactured from stainless steel. The dilator is manufactured from polyethylene and has a pre-molded proximal hub. The set also includes a 12 cc syringe, a low pressure three way stopcock, and a scalpel. The Bunegin-Albin Air Aspiration Set is sterilized by ethylene oxide and intended for one-time use.

Indications for Use:
The Bunegin-Albin Air Aspiration Set is intended to aspirate venous air emboli.

Comparison to Predicate Device:
The Bunegin-Albin Air Aspiration Set and the predicate device, the Export Advance™ Aspiration Catheter (K130536), are substantially equivalent in that these devices are similar in intended use and principle of operation. Additionally, the subject device has similar indications for use, materials, and dimensions as the predicate device. The differences between the subject device and the predicate device, including the materials, dimensions, and indications for use do not raise any new issues of safety and effectiveness. The substantial equivalence comparison of the subject device to the predicate is provided in the table below.

	PREDICATE DEVICE	SUBJECT DEVICE
	Export Advance™ Aspiration Catheter	**Bunegin-Albin Air Aspiration Set**
Manufacturer	Medtronic Incorporated	Cook Incorporated
510(k)	K130536	Subject of this submission
Regulation	21 CFR §870.5150	Identical
Product Code	DXE	Identical
Regulation Description	Catheter, Embolectomy	Identical
Classification	II	Identical
Indications for Use	The Export Advance™ Aspiration Catheter is indicated for: - Removal/aspiration of embolic material (thrombus/debris) from vessels of the arterial system, and - To sub selectively infuse/deliver diagnostics or therapeutics agents with or without vessel occlusion.	To aspirate venous air emboli.
Principle of Operation	Manually aspirate emboli with syringe	Identical
Visualization Guidance	Fluoroscopy	Identical
Method of Use	Single use	Identical
Catheter Placement	Percutaneously using Seldinger technique under fluoroscopy	Identical
Catheter Material	Polytetrafluoroethylene (PTFE)	Radiopaque extruded polyethylene
Catheter Outer Diameter	6 French	5.8 French
Catheter Length	140 cm	24, 60 cm
Catheter Distal End	Open	Open with 6 side ports
Catheter Lumens	Dual lumen	Single lumen
Wire Guide Compatibility	0.014 inch, 0.035 inch	0.035 inch
Accessory Set Components	2 Syringes 1 Wire Guide 1 Filter Cup	1 Syringe 1 Wire Guide 1 Needle 1 Dilator 1 Stopcock 1 Scalpel
Sterilization Method	EtO	Identical
Sterility Assurance Level	10^{-6}	Identical
Packaging	Tyvek pouch	Tyvek Peel Pouch

Technological Characteristics:

The subject Bunegin-Albin Air Aspiration Set was subjected to applicable testing to assure reliable design and performance under the testing parameters. The tests are listed below:

Performance

- Catheter Shaft Tensile (Zero time) – The peak load of catheter shaft section shall be greater than or equal to 15 N in accordance with BS EN ISO 10555-1. The acceptance criterion was met.
- Catheter Sideport Tensile (Zero time) – The peak load of catheter sideport section shall be greater than or equal to 15 N in accordance with BS EN ISO 10555-1. The acceptance criterion was met.
- Catheter Hub-to-Shaft Tensile (Zero time) – The peak load of catheter hub-to-shaft section shall be greater than or equal to 15 N in accordance with BS EN ISO 10555-1. The acceptance criterion was met.
- Catheter Air Aspiration (Zero time) – No air shall enter the hub when tested in accordance with Annex D of BS EN ISO 10555-1. The acceptance criterion was met.
- Catheter Liquid Leakage (Zero time) – No part of the catheter shall leak liquid when tested in accordance with Annex C of BS EN ISO 10555-1. The acceptance criterion was met.
- Catheter Kink Length (Zero time) – Catheter shall not kink when tested in accordance with Annex B of BS EN 13868. The acceptance criterion was met.
- Wire Guide Corrosion (Zero time) – Wire guide shall show no evidence of corrosion that could affect the functional performance when tested in accordance with Annex B of BS EN ISO 11070. The acceptance criterion was met.
- Wire Guide Flex (Zero time) – Wire guide shall show no signs of defects or damage, including flaking or material loss when tested in accordance with Annex G of BS EN ISO 11070. The acceptance criterion was met.
- Wire Guide Fracture (Zero time) – Wire guide shall not fracture when wound around an approximate former in accordance with Annex F of BS EN ISO 11070. The acceptance criterion was met.
- Wire Guide Tensile (Zero time) – The peak load to failure shall be greater than or equal to 10 N in accordance with Annex H of BS EN ISO 11070. The acceptance criterion was met.
- Wire Guide Rotations to Failure Testing (Zero time) – The number of rotations to failure shall be characterized for the wire guide.

- Wire Guide Tip Deflection (Zero time) – The tip deflection side loads will be characterized for the wire guide.
- Dilator Shaft Tensile (Zero time) – the peak load of dilator shaft section shall be greater than or equal to 15 N in accordance with BS EN ISO 11070. The acceptance criterion was met.
- Dilator Hub-to-Shaft Tensile (Zero time) – The peak load of dilator hub-to-shaft section shall be greater than or equal to 15 N in accordance with BS EN ISO 11070. The acceptance criterion was met.
- Dimensional, Compatibility, and Surface Analysis (Zero-time) – All measurements and dimensional requirements shall be within the listed tolerances. The set components shall be compatible for each test specimen. The external surface of the effective length of the catheter, dilator, and wire guide shall appear free of extraneous matter for each test specimen. The acceptance criterion was met.
- Particulate Testing (Zero-time) – Each device must meet the USP 788 thresholds for small volume injections. The acceptance criterion was met.
- Resistance to Overriding Testing (Zero-time) – Testing was conducted in accordance with ISO 594-2. The acceptance criterion was met.
- Separation Force Testing (Zero-time) – Testing was conducted in accordance with ISO 594-2. The acceptance criterion was met.
- Unscrewing Torque Testing (Zero-time) – Testing was conducted in accordance with ISO 594-2. The acceptance criterion was met.
- Catheter Shaft Tensile (3-year accelerated aging) – The peak load of catheter shaft section shall be greater than or equal to 15 N in accordance with BS EN ISO 10555-1. The acceptance criterion was met.
- Catheter Sideport Tensile (3-year accelerated aging) – The peak load of catheter sideport section shall be greater than or equal to 15 N in accordance with BS EN ISO 10555-1. The acceptance criterion was met.
- Catheter Hub-to-Shaft Tensile (3-year accelerated aging) – The peak load of catheter hub-to-shaft section shall be greater than or equal to 15 N in accordance with BS EN ISO 10555-1. The acceptance criterion was met.
- Catheter Air Aspiration (3-year accelerated aging) – No air shall enter the hub when tested in accordance with Annex D of BS EN ISO 10555-1. The acceptance criterion was met.

- Catheter Liquid Leakage (3-year accelerated aging) – No part of the catheter shall leak liquid when tested in accordance with Annex C of BS EN ISO 10555-1. The acceptance criterion was met.
- Catheter Kink Length (3-year accelerated aging) - Catheter shall not kink (based on a 20 mm kink radius) when tested in accordance with Annex B of BS EN 13868. The acceptance criterion was met.
- Dilator Shaft Tensile (3-year accelerated aging) – The peak load of dilator shaft section shall be greater than or equal to 15 N in accordance with BS EN ISO 11070. The acceptance criterion was met.
- Dilator Hub-to-Shaft Tensile (3-year accelerated aging) – The peak load of dilator hub-to-shaft section shall be greater than or equal to 15 N in accordance with BS EN ISO 11070. The acceptance criterion was met.

Animal Testing

- Acute performance of aspiration catheter in animal model – Catheter shall receive a grading of "adequate" or "good" in each of the performance parameters, and it shall be able to remove air from the target sites. The acceptance criterion was met.

Biocompatibility

- Per ISO 10993-1 and FDA guidance, testing for cytotoxicity, sensitization, intracutaneous irritation, acute systemic toxicity, material-mediated pyrogenicity, and hemocompatibility (hemolysis, complement activation, and *in vivo* thrombogenicity) were performed to ensure the biocompatibility of the subject device set. The acceptance criterion was met.

Conclusion:

The results of these tests support a conclusion that the Bunegin-Albin Air Aspiration Set met the design input requirements based on the intended use and support the conclusion that this device does not raise new questions of safety or effectiveness and is substantially equivalent to the predicate device, the Export Advance™ Aspiration Catheter (Medtronic Inc., K130536).