



Food and Drug Administration
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August 2, 2016

Cook Incorporated
Kotei Aoki
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, Indiana 47404

Re: K160542

Trade/Device Name: 5.0 Fr Arndt Endobronchial Blocker Set
9.0 Fr Arndt Endobronchial Blocker Set
Regulation Number: 21 CFR 868.5740
Regulation Name: Tracheal/Bronchial Differential Ventilation Tube
Regulatory Class: Class II
Product Code: CBI
Dated: July 1, 2016
Received: July 5, 2016

Dear Kotei Aoki:

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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K160542

Device Name

5.0 Fr Arndt Endobronchial Blocker Set

9.0 Fr Arndt Endobronchial Blocker Set

Indications for Use (Describe)

The 5.0 Fr Arndt Endobronchial Blocker Set is intended to differentially intubate a patient's bronchus in order to isolate the left or right lung for procedures that require one-lung ventilation. The 5.0 Fr Arndt Endobronchial Blocker is indicated for pediatric populations, in children 1 year and older.

The 9.0 Fr Arndt Endobronchial Blocker Set is intended to differentially intubate a patient's bronchus in order to isolate the left or right lung for procedures that require one-lung ventilation. The 9.0 Fr Arndt Endobronchial Blocker is indicated for adult use only.

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)

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

510(k) Summary

5.0 Fr Arndt Endobronchial Blocker Set
9.0 Fr Arndt Endobronchial Blocker Set
21 CFR §868.5740
Date Prepared: August 1, 2016

Submitted By:

Applicant: Cook Incorporated
Contact: Kotei Aoki
Applicant Address: Cook Incorporated
750 Daniels Way
Bloomington, IN 47404
Contact Phone Number: (812) 335-3575 x102630
Contact Fax Number: (812) 332-0281

Device Information:

Trade Name: 5.0 Fr Arndt Endobronchial Blocker Set
9.0 Fr Arndt Endobronchial Blocker Set
Common Name: Endobronchial Blocker
Classification Name: Tracheal/bronchial differential ventilation tube
Regulation: 21 CFR §868.5740
Product Code: CBI

Predicate Devices:

- K962167, Bronchial Blocker
- K002288, Arndt Pediatric Endobronchial Blocker

Device Description:

The 5.0 Fr Arndt Endobronchial Blocker Set and the 9.0 Fr Arndt Endobronchial Blocker Set are comprised of a blocker catheter with a silicone balloon near the distal end. The proximal end of the blocker catheter is bonded with a one-way valve and a pilot balloon assembly. A nylon guide loop at the distal end of the blocker catheter is wrapped around the tip of the bronchoscope and tightened, in order for the bronchoscope to assist in the precise placement of the blocker catheter. An Arndt Multiport Airway Adapter, a proximal straight connector, a suction adapter, and a syringe are also provided with each set.

Intended Use:

The 5.0 Fr Arndt Endobronchial Blocker Set is intended to differentially intubate a patient's bronchus in order to isolate the left or right lung for procedures that require one-lung ventilation. The 5.0 Fr Arndt Endobronchial Blocker is indicated for pediatric populations, in children 1 year and older.

The 9.0 Fr Arndt Endobronchial Blocker Set is intended to differentially intubate a patient's bronchus in order to isolate the left or right lung for procedures that require one-lung ventilation. The 9.0 Fr Arndt Endobronchial Blocker is indicated for adult use only.

Comparison to Predicates:

The proposed 5.0 Fr Arndt Endobronchial Blocker Set is substantially equivalent to the predicate device the Arndt Pediatric Endobronchial Blocker (K002288) in that these devices have the same intended use, fundamental technological characteristics, method of operation, and materials of construction.

The proposed 9.0 Fr Arndt Endobronchial Blocker Set is substantially equivalent to the predicate device the Bronchial Blocker (K962167) in that these devices have the same intended use, fundamental technological characteristics, method of operation, and similar materials of construction.

The substantial equivalence of the modified devices to the predicate device is supported by testing. A substantial equivalence comparison of each proposed device is provided in Tables 1 and 2, respectively.

Table 1 Substantial Equivalence Comparison – 5.0 Fr Arndt Endobronchial Blocker Set

		Predicate Device	Subject Device
		Arndt Pediatric Endobronchial Blocker K002288	5.0 Fr Arndt Endobronchial Blocker Set
Regulation Number		21 CFR §868.5740	Identical
Product Code		CBI	
Classification Name		Tracheal/bronchial differential ventilation tube	Identical
Class		II	Identical
Intended Use		Intended for use to differentially intubate a patient’s bronchus in order to isolate the left or right lung for procedures which require one-lung ventilation.	Identical*
Catheter Shaft	Material	Nylon	Identical
	Centimeter Marker	Yes	Identical
	Inner Diameter (in)	0.028	Identical
	Outer Diameter (Fr)	5.0	Identical
	Length (cm)	50	50, 65
	Tip Shape	Straight	Identical
	Number of Sideports	None	Identical
Guide Loop Snare	Snare Material	Nylon	Identical
	Adapter Material	Polyamide	Identical
	Cap Material	Acetal	Identical
	Usable Loop length along Semi-Major Axis (mm)	5	10
	May Be Reinserted (reinforcement material)	No	Identical
Distal Balloon	Material	Silicone	Identical
	Length (mm)	8	Identical
	Shape	Elliptical, Spherical	Spherical
	Inflation Media	Air	Identical
	Inflation Volume (cc)	2	0.5 – 2
	Inflation Diameter (in)	0.150	Identical
Manifold Assembly	Y-shape fitting Material	Polyamide	Identical
	Pilot Balloon Assembly Material	Silicone	Identical
Used in Conjunction with Endotracheal Tube		Yes	Identical
Used in Conjunction with Bronchoscope		Yes	Identical
Accessory Components		Arndt Multiport Airway Adapter, Proximal Straight Connector, Syringe	Arndt Multiport Airway Adapter, Proximal Straight Connector, Syringe, Suction Adapter
Packaging		Tyvek/polyethylene film pouch	Identical
Sterilization		EtO	Identical

* The 5.0 French Arndt Endobronchial Blocker is indicated for pediatric populations, in children 1 year and older. The predicate (K002288) was also indicated for pediatric use.

Table 2 Substantial Equivalence Comparison – 9.0 Fr Arndt Endobronchial Blocker Set

		Predicate Device	Subject Device
		Bronchial Blocker K962167	9.0 Fr Arndt Endobronchial Blocker Set
Regulation Number Product Code		21 CFR §868.5740 CBI	Identical
Classification Name		Tracheal/bronchial differential ventilation tube	Identical
Class		II	Identical
Intended Use		Intended for use to differentially intubate a patient’s bronchus in order to isolate the left or right lung for procedures which require one-lung ventilation.	Identical
Catheter Shaft	Material	Polyethylene	Nylon
	Centimeter Marker	Yes	Identical
	Inner Diameter (in)	0.068	Identical
	Outer Diameter (Fr)	9.0	Identical
	Length (cm)	78	65, 78
	Tip Shape	Straight	Identical
	Number of Sideports	None	2
Guide Loop Snare	Snare Material	Nylon	Identical
	Adapter Material	Acetal	Polyamide
	Cap Material	Acetal	Identical
	Usable Loop length along Semi-Major Axis (mm)	15	Identical
	May Be Reinserted (reinforcement material)	No	Yes (Polyetheretherketone)
Distal Balloon	Material	Silicone	Identical
	Length (mm)	23	Identical
	Shape	Elliptical, Spherical	Spherical
	Inflation Media	Air	Identical
	Inflation Volume (cc)	6	4 – 8
	Inflation Diameter (in)	0.350 – 0.450	Identical
Manifold Assembly	Y-shape fitting Material	Acetal	Polyamide
	Pilot Balloon Assembly Material	Silicone	Identical
Used in Conjunction with Endotracheal Tube		Yes	Identical
Used in Conjunction with Bronchoscope		Yes	Identical
Accessory Components		Arndt Multiport Airway Adapter, Proximal Straight Connector, Syringe	Arndt Multiport Airway Adapter, Proximal Straight Connector, Syringe, Suction Adapter
Packaging		Tyvek/polyethylene film pouch	Identical
Sterilization		EtO	Identical

Technological Characteristics:

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

- Tensile Tests (the Catheter Shaft, the Distal Sideport, the Snare-to-Proximal Manifold Bond, the Hub-to-Shaft Bond, and the Pilot Balloon Assembly-to-Manifold) (Zero-Time, Three-Year Accelerated Aged) – The peak load value of the test articles was demonstrated to be greater than or equal to the established acceptance criteria.
- Analysis of Re-insertion Method of Snare (Zero-Time) – This test was performed for characterization only.
- Balloon Shear Loading Test (Zero-Time, Three-Year Accelerated Aged) – The test articles do not completely separate from the catheter shaft (both proximal and distal balloon bonds fail, i.e.) or, if the balloon ruptures, not fragment. The acceptance criteria were met.
- Pressurization Testing (Zero-Time, Three-Year Accelerated Aged) – The test articles do not exhibit signs of leakage or burst while pressurized. The acceptance criteria were met.
- Balloon Inflation Test (Zero-Time, Three-Year Accelerated Aged) – The inflation diameter of the test articles were demonstrated to be greater than the established acceptance criteria.
- Balloon Burst Testing (Zero-Time, Three-Year Accelerated Aged) – The minimum failure volume of the test articles were demonstrated to be greater than the established acceptance criteria.

The results of these tests support a conclusion that the 5.0 Fr Arndt Endobronchial Blocker Set and the 9.0 Fr Arndt Endobronchial Blocker Set met the design input requirements based on the intended use and support the conclusion that these devices do not raise new questions of safety or effectiveness as compared to the predicate device. The subject devices are therefore substantially equivalent to the predicate devices, the Bronchial Blocker (Cook Incorporated, K962167) and the Arndt Pediatric Endobronchial Blocker (Cook Incorporated, K002288).