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

August 11, 2017

Cook Incorporated
Kotei Aoki
Regulatory Affairs Specialist
750 Daniels Way, P.O. Box 489
Bloomington, Indiana 47404

Re: K162729
Trade/Device Name: Aintree Intubation Catheter, Arndt Airway Exchange Catheter Set, Cook Airway Exchange Catheter, and Cook Airway Exchange Catheter - Extra Firm With Soft Tip
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: Class II
Product Code: BTR
Dated: July 12, 2017
Received: July 13, 2017

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,

Tara A. Ryan -S

for
Lori Wiggins
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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)*

K162729

Device Name
Cook Airway Exchange Catheter

Indications for Use *(Describe)*

The Cook Airway Exchange Catheter is intended for endotracheal tube exchange in adult and pediatric patients.

The 8 French catheter is recommended for placement of an endotracheal tube with an inner diameter of 3 mm or larger.

When used for high-pressure oxygenation with a Luer Lock connector, the 8 French catheter is recommended for patients older than 1 month of age.

The 11 French catheter is recommended for placement of an endotracheal tube with an inner diameter of 4 mm or larger.

When used for high-pressure oxygenation with a Luer Lock connector, the 11 French catheter is recommended for patients older than 2 years of age.

The 14 French catheter is recommended for placement of an endotracheal tube with an inner diameter of 5 mm or larger.

When used for high-pressure oxygenation with a Luer Lock connector, the 14 French catheter is recommended for patients older than 2 years of age.

The 19 French catheter is recommended for placement of an endotracheal tube with an inner diameter of 7 mm or larger.

When used for high-pressure oxygenation with a Luer Lock connector, the 19 French catheter is recommended for patients older than 12 years of age.

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:

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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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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)*

K162729

Device Name
Cook Airway Exchange Catheter - Extra-Firm with Soft Tip

Indications for Use *(Describe)*

The Cook Airway Exchange Catheter - Extra-Firm with Soft Tip is intended for endotracheal tube exchange in adult and pediatric patients.

The 11 French catheter is recommended for placement of an endotracheal tube with an inner diameter of 4 mm or larger.

When used for high-pressure oxygenation with a Luer Lock connector, the 11 French catheter is recommended for patients older than 2 years of age.

The 14 French catheter is recommended for placement of an endotracheal tube with an inner diameter of 5 mm or larger.

When used for high-pressure oxygenation with a Luer Lock connector, the 14 French catheter is recommended for patients older than 2 years of age.

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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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)*
K162729

Device Name
Arndt Airway Exchange Catheter Set

Indications for Use *(Describe)*
The Arndt Airway Exchange Catheter Set is intended for exchange of a supraglottic airway device (SAD) to an endotracheal tube (ETT) under bronchoscopic assistance, and for ETT exchange in adult and pediatric patients.

The product may be used for emergency, urgent, and elective airway management.

The 14 French catheter is recommended for placement of an endotracheal tube or a supraglottic airway device with an inner diameter of 5 mm or larger.

When used for high-pressure oxygenation with a Luer lock connector, the 14 French catheter is recommended for patients older than 12 years of age.

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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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162729

Device Name
Aintree Intubation Catheter

Indications for Use *(Describe)*
The Aintree Intubation Catheter is intended for exchange of a supraglottic airway device (SAD) to an endotracheal tube (ETT) under bronchoscopic assistance, and for ETT exchange in adult and pediatric patients.

The 19 French catheter is recommended for use with a supraglottic airway device and placement of a single-lumen endotracheal tube with an inner diameter of 7 mm or larger.

When used for high-pressure oxygenation with a Luer lock connector, the 19 French catheter is recommended for patients older than 12 years of age.

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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Respiratory Management Sets
21 CFR §868.5730
Date Prepared: 4 August 2017

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:

Device Trade Name	Classification Name	Regulation	Product Code	Common Name
Aintree Intubation Catheter	Tube, Tracheal (w/wo connector)	21 CFR §868.5730	BTR	Respiratory Management Sets
Arndt Airway Exchange Catheter Set	Tube, Tracheal (w/wo connector)	21 CFR §868.5730	BTR	
Cook Airway Exchange Catheter	Tube, Tracheal (w/wo connector)	21 CFR §868.5730	BTR	
Cook Airway Exchange Catheter – Extra-Firm with Soft Tip	Tube, Tracheal (w/wo connector)	21 CFR §868.5730	BTR	

Predicate Device:

- K862347, Tube Exchanger (Sheridan Catheter Corp.)

Device Description:

The Respiratory Management Sets are a family of airway management products, designed for establishing, re-establishing, or maintaining an airway. The catheters may be manufactured from polyurethane or polyethylene. They are single lumen catheters and are designed with a blunt or tapered distal tip. Incremental markings on the catheter shafts facilitate the accurate placement of the catheters into the airway. The subject device catheters have sideports at the distal end and the subject devices are provided with two Rapi-Fit adapters for ventilation when oxygen requirement is high and the supraglottic airway device or endotracheal tube is not in the trachea of the patients.

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The subject device catheters are designed to be compatible with a specified range of endotracheal tubes for adult and pediatric patients, as shown in the table below.

Subject device	Catheter size		Recommended Minimum Endotracheal Tube Size (I.D.)
	O.D	Length	
Aintree Intubation Catheter	19 Fr	56 cm	7.0 mm
Arndt Airway Exchange Catheter Set	14 Fr	70 cm	5.0 mm
Cook Airway Exchange Catheter	8 Fr	45 cm	3.0 mm
	11 Fr	83 cm	4.0 mm
	14 Fr	83 cm	5.0 mm
	19 Fr	83 cm	7.0 mm
Cook Airway Exchange Catheter – Extra-Firm with Soft Tip	11 Fr	100 cm	4.0 mm
	14 Fr	100 cm	5.0 mm

The Aintree Intubation Catheter is comprised of an intubation catheter, two Rapi-Fit adapters (one with a 15 mm connector, and one with a Luer lock connector), and a double swivel connector. The intubation catheter is made of polyurethane and is 19 Fr in diameter and 56 cm long. The distal end of the intubation catheter is open and designed with a straight and tapered tip, with two sideports aligned opposite to each other.

The Arndt Airway Exchange Catheter Set is comprised of an exchange catheter, a wire guide, two Rapi-Fit adapters (one with a 15 mm connector, and one with a Luer lock connector), and a double swivel connector. The catheter is made of polyurethane and is 14 Fr in diameter and 70 cm long. The distal end of the exchange catheter is open and designed with a straight and tapered tip, with six sideports spiraled along the distal tip.

The Cook Airway Exchange Catheter is comprised of an exchange catheter and two Rapi-Fit adapters (one with a 15 mm connector, and one with a Luer lock connector). The 8, 11, and 14 Fr catheters are made of polyurethane, while the 19 Fr catheter is made of polyethylene. The 8 Fr catheter is 45 cm long, while the 11, 14, and 19 Fr catheters are 83 cm long. The distal ends of the exchange catheters are open and designed with a straight and tapered tip. The 8 Fr, 14 Fr, and 19 Fr catheters have two sideports aligned opposite to each other, while the 11 Fr catheter has six sideports spiraled along the distal end.

The Cook Airway Exchange Catheter – Extra-Firm with Soft Tip are comprised of an exchange catheter and two Rapi-Fit adapters (one with a 15 mm connector, and one with a Luer lock connector). The exchange catheter is made of polyurethane intermittent extrusion tubing, with a stiff shaft and a softer distal tip (distal 7 cm of the catheter is made of a softer and more flexible polyurethane). The catheter is available in diameters

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of 11 or 14 Fr, and a length or 100 cm. The distal ends of the exchange catheters are open and designed with a straight and blunt tip. The 11 Fr catheter has six sideports spiraled along the distal end, while the 14 Fr catheter has two sideports aligned opposite to each other.

Intended Use:

The Respiratory Management Sets are intended to assist / facilitate placement of a supraglottic airway device or an endotracheal tube through intubation or exchange.

Indication for Use:

Respiratory Management Sets	**Indication for Use**
Aintree Intubation Catheter	The Aintree Intubation Catheter is intended for exchange of a supraglottic airway device (SAD) to an endotracheal tube (ETT) under bronchoscopic assistance, and for ETT exchange in adult and pediatric patients. The 19 French catheter is recommended for use with a supraglottic airway device and placement of a single-lumen endotracheal tube with an inner diameter of 7 mm or larger. When used for high pressure oxygenation with a Luer Lock connector, the 19 French catheter is recommended for patients older than 12 years of age.

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Respiratory Management Sets	Indication for Use
Arndt Airway Exchange Catheter Set	The Arndt Airway Exchange Catheter Set is intended for exchange of a supraglottic airway device (SAD) to an endotracheal tube (ETT) under bronchoscopic assistance, and for ETT exchange in adult and pediatric patients. The product may be used for emergency, urgent, and elective airway management. The 14 French catheter is recommended for placement of an endotracheal tube or a supraglottic airway device with an inner diameter of 5 mm or larger. When used for high pressure oxygenation with a Luer Lock connector, the 14 French catheter is recommended for patients older than 12 years of age.
Cook Airway Exchange Catheter	The Cook Airway Exchange Catheter is intended for endotracheal tube exchange in adult and pediatric patients. The 8 French catheter is recommended for placement of an endotracheal tube with an inner diameter of 3 mm or larger. When used for high pressure oxygenation with a Luer Lock connector, the 8 French catheter is recommended for patients older than 1 month of age. The 11 French catheter is recommended for placement of an endotracheal tube with an inner diameter of 4 mm or larger. When used for high pressure oxygenation with a Luer Lock connector, the 11 French catheter is recommended for patients older than 2 years of age. The 14 French catheter is recommended for placement of an endotracheal tube with an inner diameter of 5 mm or larger. When used for high pressure oxygenation with a Luer Lock connector, the 14 French catheter is recommended for patients older than 2 years of age. The 19 French catheter is recommended for placement of an endotracheal tube with an inner diameter of 7 mm or larger. When used for high pressure oxygenation with a Luer Lock connector, the 19 French catheter is recommended for patients older than 12 years of age.

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Respiratory Management Sets	Indication for Use
Cook Airway Exchange Catheter – Extra-Firm with Soft Tip	The Cook Airway Exchange Catheter – Extra-Firm with Soft Tip is intended for endotracheal tube exchange in adult and pediatric patients. The 11 French catheter is recommended for placement of an endotracheal tube with an inner diameter of 4 mm or larger. When used for high pressure oxygenation with a Luer Lock connector, the 11 French catheter is recommended for patients older than 2 years of age. The 14 French catheter is recommended for placement of an endotracheal tube with an inner diameter of 5 mm or larger. When used for high pressure oxygenation with a Luer Lock connector, the 14 French catheter is recommended for patients older than 2 years of age.

Comparison to Predicates:

The Respiratory Management Sets are substantially equivalent to the predicate device in that they have the same intended use as the predicate device, which is to assist / facilitate exchange of a supraglottic airway device (SAD) or an endotracheal tube(ETT), even though the exact wording might differ slightly. The predicate is indicated for extubation and exchange of ETT. The exchange portion of the indication for use of the predicate is the same as the subject device catheters. The subject device catheters are also indicated for pediatric use while the predicate is not. This difference does not raise different questions of safety or effectiveness between the predicate and subject device because selection of the size of the exchange catheters depends on the size of the ETT or SAD that is appropriate for each patient based on weight and age. In addition, verification and validation testing on the subject device catheters support the conclusion that the differences in technological characteristics between the predicate and subject device catheters do not raise different questions on safety and effectiveness. The substantial equivalence comparison with each subject device and its respective predicate device is provided in Tables 1 through 4.

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Table 1: Substantial Equivalence Comparison Table – Aintree Intubation Catheter

	Predicate	Subject Device
	Sheridan Catheter Corp. Tube Exchanger (K862347)	**Aintree Intubation Catheter**
Regulation	21 CFR 868.5730	Identical
Product Code	BTR	Identical
Classification	II	Identical
Intended Use/Indications for Use	For extubation and exchange of endotracheal tubes.	The Aintree Intubation Catheter is intended for intended for exchange of a supraglottic airway device (SAD) to an endotracheal tube (ETT) under bronchoscopic assistance, and for ETT exchange in adult and pediatric patients. The 19 French catheter is recommended for use with a supraglottic airway device and placement of a single-lumen endotracheal tube with an inner diameter of 7 mm or larger. When used for high pressure oxygenation with a Luer Lock connector, the 19 French catheter is recommended for patients older than 12 years of age.
One-time use	Yes	Identical
Catheter insertion method	Orally or nasally	Identical
Adapter provided for oxygenation through catheter	Yes	Identical
Catheter distal tip	Straight and blunt	Identical
Catheter depth marking	Yes	Identical
Patient population	Not specified	Pediatric and adult
Visualization guidance	Not specified	Bronchoscopy
Catheter outer diameter	11, 14, and 19 Fr	19 Fr – for pediatric and adult use
Inner diameter of compatible endotracheal tube	11 Fr – ≥ 4 mm 14 Fr – ≥ 5 mm 19 Fr – ≥ 7 mm	19 Fr – ≥7 mm
Catheter length	80 cm	56 cm
Catheter material	Polyvinyl Chloride	Polyurethane
Catheter distal end	Open with 4 sideports	Open with 2 sideports
Accessory set components	1 15 mm adapter (for convenience should patient oxygenation be necessary during exchange procedure)	1 double swivel connector 2 Rapi-Fit adapters (one with 15 mm connector and one with Luer lock connector) provided if patient must be oxygenated during intubation procedure
Sterilization Method	Ethylene Oxide	Identical
Packaging	Unknown	Sealed in a Tyvek pouch

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Table 2: Substantial Equivalence Comparison Table – Arndt Airway Exchange Catheter Set

	Predicate	Subject Device
	Sheridan Catheter Corp. Tube Exchanger (K862347)	**Arndt Airway Exchange Catheter Set**
Regulation	21 CFR 868.5730	Identical
Product Code	BTR	Identical
Classification	II	Identical
Intended Use/Indications for Use	For extubation and exchange of endotracheal tubes	The Arndt Airway Exchange Catheter Set is intended for exchange of a supraglottic airway device (SAD) to an endotracheal tube (ETT) under bronchoscopic assistance, and for ETT exchange in adult and pediatric patients. The product may be used for emergency, urgent, and elective airway management. The 14 French catheter is recommended for placement of an endotracheal tube or a supraglottic airway device with an inner diameter of 5 mm or larger. When used for high pressure oxygenation with a Luer Lock connector, the 14 French catheter is recommended for patients older than 12 years of age.
One-time use	Yes	Identical
Catheter insertion method	Orally or nasally	Identical
Adapter provided for oxygenation through catheter	Yes	Identical
Catheter depth marking	Yes	Identical
Patient population	Not specified	Pediatric and adult
Visualization guidance	Not specified	Bronchoscopy
Catheter distal tip	Straight and blunt	Straight and tapered
Catheter outer diameter	11, 14, and 19 Fr	14 Fr
Inner diameter of compatible endotracheal tube	11 Fr – ≥ 4 mm 14 Fr – ≥ 5 mm 19 Fr – ≥ 7 mm	14 Fr – ≥ 5 mm
Catheter length	80 cm	70 cm
Catheter material	Polyvinyl Chloride	Polyurethane
Catheter distal end	Open with 4 sideports	Open with 6 sideports
Accessory set components	1 15 mm adapter (for convenience should patient oxygenation be necessary during exchange procedure)	1 wire guide 1 double swivel connector 2 Rapi-Fit adapters (one with 15 mm connector and one with Luer lock connector) provided if patient must be oxygenated during intubation procedure
Sterilization Method	Ethylene Oxide	Identical
Packaging	Unknown	Placed within a tray and then sealed in a Tyvek pouch

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Table 3: Substantial Equivalence Comparison Table – Cook Airway Exchange Catheter

	Predicate	Subject Device
	Sheridan Catheter Corp. Tube Exchanger (K862347)	**Cook Airway Exchange Catheter**
Regulation	21 CFR 868.5730	Identical
Product Code	BTR	Identical
Classification	II	Identical
Intended Use/Indications for Use	For extubation and exchange of endotracheal tubes	The Cook Airway Exchange Catheter is intended for endotracheal tube exchange in adult and pediatric patients. The 8 French catheter is recommended for placement of an endotracheal tube with an inner diameter of 3 mm or larger. When used for high pressure oxygenation with a Luer Lock connector, the 8 French catheter is recommended for patients older than 1 month of age. The 11 French catheter is recommended for placement of an endotracheal tube with an inner diameter of 4 mm or larger. When used for high pressure oxygenation with a Luer Lock connector, the 11 French catheter is recommended for patients older than 2 years of age. The 14 French catheter is recommended for placement of an endotracheal tube with an inner diameter of 5 mm or larger. When used for high pressure oxygenation with a Luer Lock connector, the 14 French catheter is recommended for patients older than 2 years of age. The 19 French catheter is recommended for placement of an endotracheal tube with an inner diameter of 7 mm or larger. When used for high pressure oxygenation with a Luer Lock connector, the 19 French catheter is recommended for patients older than 12 years of age.
One-time use	Yes	Identical
Catheter insertion method	Orally or nasally	Identical
Adapter provided for oxygenation through catheter	Yes	Identical
Catheter distal tip	Straight and blunt	Identical
Catheter depth marking	Yes	Identical

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	Predicate	Subject Device
	Sheridan Catheter Corp. Tube Exchanger (K862347)	**Cook Airway Exchange Catheter**
Patient population	Not specified	Pediatric and adult
Catheter outer diameter	11, 14, and 19 Fr	8 Fr – pediatric use 11 Fr – pediatric and adult use 14 Fr – pediatric and adult use 19 Fr – pediatric and adult use
Inner diameter of compatible endotracheal tube	11 Fr – ≥ 4 mm 14 Fr – ≥ 5 mm 19 Fr – ≥ 7 mm	8 Fr – ≥ 3 mm 11 Fr – ≥ 4 mm 14 Fr – ≥ 5 mm 19 Fr – ≥ 7 mm
Catheter length	80 cm	8 Fr – 45 cm 11 Fr – 83 cm 14 Fr – 83 cm 19 Fr – 83 cm
Catheter material	Polyvinyl Chloride	8 Fr – polyurethane 11 Fr – polyurethane 14 Fr – polyurethane 19 Fr - polyethylene
Catheter distal end	Open with 4 sideports	8 Fr – open with 2 sideports 11 Fr – open with 6 sideports 14 Fr – open with 2 sideports 19 Fr - open with 2 sideports
Accessory set components	1 15 mm adapter (for convenience should patient oxygenation be necessary during exchange procedure)	2 Rapi-Fit adapters (one with 15 mm connector and one with Luer lock connector) provided if patient must be oxygenated during intubation procedure
Sterilization Method	Ethylene Oxide	Identical
Packaging	Unknown	Sealed in a Tyvek pouch

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Table 4: Substantial Equivalence Comparison Table – Cook Airway Exchange Catheter – Extra-Firm with Soft Tip

	Predicate	Subject Device
	Sheridan Catheter Corp. Tube Exchanger (K862347)	**Cook Airway Exchange Catheter – Extra-Firm with Soft Tip**
Regulation	21 CFR 868.5730	Identical
Product Code	BTR	Identical
Classification	II	Identical
Intended Use/Indications for Use	For extubation and exchange of endotracheal tubes	The Cook Airway Exchange Catheter – Extra-Firm with Soft Tip is intended for endotracheal tube exchange in adult and pediatric patients. The 11 French catheter is recommended for placement of an endotracheal tube with an inner diameter of 4 mm or larger. When used for high pressure oxygenation with a Luer Lock connector, the 11 French catheter is recommended for patients older than 2 years of age. The 14 French catheter is recommended for placement of an endotracheal tube with an inner diameter of 5 mm or larger. When used for high pressure oxygenation with a Luer Lock connector, the 14 French catheter is recommended for patients older than 2 years of age.
One-time use	Yes	Identical
Catheter insertion method	Orally or nasally	Identical
Adapter provided for oxygenation through catheter	Yes	Identical
Catheter distal tip	Straight and blunt	Identical
Catheter depth marking	Yes	Identical
Patient population	Not specified	Pediatric and adult
Catheter material	Polyvinyl Chloride	Polyurethane
Catheter outer diameter	11, 14, and 19 Fr	11, 14 Fr
Catheter length	80 cm	100 cm
Catheter distal end	Open with 4 sideports	11 Fr – open with 6 sideports 14 Fr – open with 2 sideports
Inner diameter of compatible endotracheal tube	11 Fr – ≥ 4 mm 14 Fr – ≥ 5 mm 19 Fr – ≥ 7 mm	11 Fr – ≥ 4 mm 14 Fr – ≥ 5 mm
Accessory set components	1 15 mm adapter (for convenience should patient oxygenation be necessary during exchange procedure)	2 Rapi-Fit adapters (one with 15 mm connector and one with Luer lock connector) provided if patient must be oxygenated during intubation procedure
Sterilization Method	Ethylene Oxide	Identical
Packaging	Unknown	Sealed in a Tyvek pouch

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Technological Characteristics:

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

Performance Testing:

- Catheter shaft tensile (Zero time and aged) – the peak load of specified catheter shaft section shall be greater than or equal to the applicable load requirement (based on outer diameter) in accordance with BS EN ISO 10555-1. The acceptance criterion was met.
- Catheter sideport tensile (Zero time and aged) – the peak load of specified catheter shaft section shall be greater than or equal to the applicable load requirement (based on outer diameter) in accordance with BS EN ISO 10555-1. The acceptance criterion was met.
- Catheter shaft radiopacity (Zero time and aged) – the radiopacity of the catheter shaft shall fall along the gradient of an aluminum X-ray step wedge gauge. The acceptance criterion was met.
- Catheter shaft kink radius (Aged) – the catheter shaft meets the kink requirement in accordance with Annex H of ISO 5361:2012. The acceptance criteria were met.
- Rapi-Fit adapter-to-catheter attachment (Aged) – the separation for between the adapter and the catheter shall be greater than that of the catheter tensile force requirement. The acceptance criterion was met.
- High pressure oxygenation insufflation on catheters (Zero time and aged) – the ASL 5000 Breathing Simulator from IngMar Medical was used to simulate breathing profiles of infant (> 1 month to 2 years old), child (> 2 years to 12 years old), adolescent (> 12 years through 21 years old), and adult (> 21 years old) patient sub-groups. Delivered minute volume and average maximum airway pressure were measured for each patient sub-group.
- Catheter dimensional and ink marking verification (Zero time) – Catheter length and ink marking on catheters was verified. The acceptance criterion was met.
- Wire guide corrosion (Zero time and aged) – wire guides should not have any visual 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.

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- Wire guide tensile (Zero time and aged) – the peak load of 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 flex (Zero time and aged) – wire guides shall not show signs of defects or damage when subjected to repeat flexing in accordance with Annex G of BS EN ISO 11070. The acceptance criterion was met.
- Wire guide fracture (Zero time and aged) – wire guides shall not fracture when wound around an appropriate former in accordance with Annex F of BS EN ISO 11070. The acceptance criterion was met.
- Luer Lock hub of Rapi-Fit Adapter unscrewing torque (Zero time and aged) - Testing was conducted in accordance with Sections 4.4 and 5.5 of ISO 594-2. The acceptance criterion was met.
- Luer Lock hub of Rapi-Fit Adapter resistance to overriding (Zero time and Aged) - Testing was conducted in accordance with Sections 4.6 and 5.7 of ISO 594-2. The acceptance criterion was met.
- Luer Lock hub of Rapi-Fit Adapter separation force (Zero time and aged) - Testing was conducted in accordance with Sections 4.3 and 5.4 of ISO 594-2. The acceptance criterion was met.
- 15-mm hub of Rapi-Fit Adapter compliance verification (Zero time and aged) - Testing was conducted in accordance with Section 3.1.2 of ISO 5356:2015. The acceptance criterion was met.
- Double Swivel Connector compatibility analysis of (Aged) – catheters shall be able to be inserted and removed through the septum of the double swivel connector into an endotracheal tube. The acceptance criterion was met.

Biocompatibility testing

- Per ISO 10993-1 and FDA guidance, testing for cytotoxicity, sensitization, intracutaneous irritation, acute systemic toxicity (when applicable), and material-mediated pyrogenicity (when applicable) were performed to ensure the biocompatibility of the subject devices.

The results of these tests show that the subject devices meet the design input requirements based on the intended use and support the conclusion that these devices do

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not raise new questions of safety or effectiveness and are substantially equivalent to the predicate device.