DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 22, 2016

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

Re: K153761
Trade/Device Name: Emergency Transtracheal Airway Catheter
Regulation Number: 21 CFR 868.5090
Regulation Name: Emergency Airway Needle
Regulatory Class: Class II
Product Code: BWC
Dated: August 19, 2016
Received: August 22, 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,

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

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)*

K153761

Device Name
Emergency Transtracheal Airway Catheter

Indications for Use *(Describe)*
The Emergency Transtracheal Airway Catheter is intended for emergency airway access when conventional endotracheal intubation cannot be performed.

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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510(k) Summary

Emergency Transtracheal Airway Catheter
21 CFR §868.5090
Date Prepared: September 21, 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:	Emergency Transtracheal Airway Catheter
Common name:	Tracheal Catheter Needle
Classification Name:	Emergency Airway Needle
Regulation:	21 CFR §868.5090
Product Code:	BWC

Predicate Devices:

The device subject of this submission is substantially equivalent to the predicate device, Patil Emergency Cricothyrotomy Catheter Set, cleared for market under 510(k) number K013252 on February 21, 2002.

Device Description:

The Emergency Transtracheal Airway Catheter is composed of a catheter and needle. The catheter-needle assembly cannulates the trachea through the cricothyroid membrane in order to establish an airway. The catheter is designed as a 6.0 French catheters manufactured from reinforced fluorinated ethylene propylene (FEP) tubing fitted to a 15 gage stainless steel needle with a lancet bevel. The nominal length of the catheter measures 5.0 or 7.5 centimeters, depending upon device specification. The catheter French size is stamped on the proximal fitting of the catheter. The Luer hub on the proximal end of the catheter connects to an oxygen source.

The needle is manufactured with a nickel plated brass hub. The lancet bevel of the needle extends from the catheter at the heel of the bevel. The needle and the hub are soldered

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with tin-silver alloy material. The catheter-needle assembly cannulates the trachea through the cricothyroid membrane in order to establish an airway. The needle is removed from the catheter after the catheter-needle assembly establishes an airway through the cricothyroid membrane, leaving the catheter in the trachea.

Intended Use:

The Emergency Transtracheal Airway Catheter is intended for emergency airway access when conventional endotracheal intubation cannot be performed.

Comparison to Predicates:

The Emergency Transtracheal Airway Catheters are substantially equivalent to the predicate device, Patil Emergency Cricothyrotomy Catheter Set (K013252), in that these devices have the identical intended use, method of operation, and the same fundamental technological characteristics. The modifications to the needle, the airway catheter, and the needle hub have been included.

Furthermore, aside from the needle hub and the solder, no other changes to the material components of the subject device have been made with respect to the predicate device. However, biocompatibility testing has been performed to confirm the device remains biocompatible.

The substantial equivalence of the modified device to the predicate device is supported by testing. Table 1 is a chart that compares the subject device to the predicate device side-by-side.

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Table 1 Substantial Equivalence Comparison

		Predicate Devices	Subject Device
		Patil Emergency Cricothyrotomy Catheter Set (K013252)	**Emergency Transtracheal Airway Catheter**
Regulation		21 CFR §868.5090 Needle, Emergency Airway	Identical
Product Code		BWC	Identical
Classification		II	Identical
Intended Use		Intended for emergency airway access when conventional endotracheal intubation cannot be performed.	Identical
Product Pictures (assembled)			
Catheter	**Material**	Reinforced Fluorinated Ethylene Propylene Tubing	Identical
	Diameter (Fr)	6.0, 9.0	6.0
	Length (cm)	6.0	5.0, 7.5
	Hub Material	Delrin, Polyvinylchloride, Polysulfone, Polyamide, Acetal	Polyamide
	Hub Connection	Loctite #M-31CL	Identical
	Curvature	Curved	Straight
Needle	**Gage**	19	15
	Material	Stainless Steel	Identical
	Hub Material	Polypropylene	Brass, Nickel Plated
	Hub Connection	Rencast 140	Tin-Silver solder
Sterilization Method		Ethylene Oxide	Identical
Shelf Life		3 years	3 years
Packaging		Sealed inside a Tyvek® Lidstock	Sealed inside a Tyvek® peel open pouch

Technological Characteristics:

The Emergency Transtracheal Airway Catheter is intended for emergency airway access when conventional endotracheal intubation cannot be performed. The following tests have been conducted to ensure reliable design and performance under the specified design requirements:

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- Design Validation–(Zero Time) The test articles shall be able to access the trachea of an AirSim Advance Combo model when following the instructions provided in the Instructions for Use. The acceptance criterion was met.
- Bending Rigidity of the Needle (Zero Time) – The purpose of the study was to verify that the peak load during compression within the specified deflection be greater than 7.5 N. The acceptance criterion was met.
- Insertion Force of the Needle (Zero Time) – The purpose of the study was to determine the maximum compressive load. The acceptance criterion was met.
- Breaking Resistance (Zero Time) – The purpose of the study was to confirm that the cannula of the device would withstand the forces experienced during clinical use without breaking. The predetermined acceptance criterion was met.
- Air Leakage of the Catheter (Zero Time) – The purpose of the study was to verify that the test articles meet the air leakage requirements of BS EN ISO 10555-1. The acceptance criterion was met.
- Resistance to Overriding (Zero-Time) – The purpose of the study was was to verify that the test articles meet the resistance to overriding requirements set forth in ISO 594-2. The acceptance criterion was met.
- Unscrewing Torque (Zero-Time) – The purpose of the study was to verify that the test articles meet the unscrewing torque requirements set forth in ISO 594-2. The acceptance criterion was met.
- Separation Force (Zero-Time) – The purpose of the study was to verify that the test articles meet the separation force requirements set forth in ISO 594-2. The predetermined acceptance criterion was met.
- Tensile Test of the Shaft of the Catheter (Three-year Accelerated Aging) –The purpose of study was to determine the peak tensile force of the shaft of the test articles after accelerated aging to the real-time equivalent of 3 years. The acceptance criterion was met.
- Tensile Test of the Hub to Shaft Bond of the Catheter (Three-year Accelerated Aging) – The purpose of study was to determine the peak load of the hub-to-shaft bond of the test specimens after accelerated aging to the real-time equivalent of 3 years. The acceptance criterion was met.
- Tensile Test of the Hub to Cannula Bond of the Needle (Three-year Accelerated Aging) – (Appendix D of the original submission, K153761) Testing per ISO

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11070 showed that the needle cannula does not loosen from the hub when a tensile load of at least 20 N is applied. The acceptance criterion was met.

- Air Leakage of the Catheter (Three-year Accelerated Aging and Two-year Real Time Aging) – The purpose of study was to verify that the test articles meet the air leakage requirements of BS EN ISO 10555-1 after accelerated aging to the real-time equivalent of 3 years. The acceptance criterion was met.
- Biocompatibility Testing – Per ISO 10993-1 and FDA guidance, testing for cytotoxicity, sensitization, intracutaneous irritation, acute systemic toxicity and material-mediated pyrogenicity were performed to insure the biocompatibility of the subject device. The predetermined acceptance criteria were met.
- Five Year Accelerated Aging Report for Packaging Validation – The purpose of study is to the accelerated aging of the packaging system to the real time equivalent of greater than or equal to 5 years. The acceptance criterion was met.
- Sterility Testing – Testing confirms that the device meets the appropriate requirements for bioburden, endotoxins, and EO and ECH residuals.

The results of these tests support a conclusion that the subject device meets 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 and are substantially equivalent to the predicate device (K013252).