April 23, 2018

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

Re: K171917
Trade/Device Name: Frova Intubating Introducer
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: Class II
Product Code: BTR
Dated: March 22, 2018
Received: March 23, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171917

Device Name
Frova Intubating Introducer

Indications for Use *(Describe)*
To facilitate endotracheal intubation in adult and pediatric patients where visualization of the glottis is inadequate.

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.

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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Frova Intubating Introducer
21 CFR §807.92
Date Prepared: April 20, 2018

Submitted By:

Applicant:	Cook Incorporated
Contact:	Hui Ouyang, PhD, RAC Paul Meyer
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact Phone Number:	(812) 335-3575 x105421
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Device Information:

Trade Name:	Frova Intubating Introducer
Device Common Names:	Frova Intubating Introducer
Classification Regulation:	21 CFR 868.5730, BTR
Device Classification:	Class II
Review Panel:	Anesthesiology
Office of Device Evaluation:	Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices (DAGRID) Anesthesiology Devices Branch (ANDB)

Predicate Device:

The Frova Intubating Introducer is substantially equivalent to the predicate device, the Frova Intubating Introducer (William Cook Europe Aps, K161813), cleared by FDA on May 19, 2017.

Device Description:

The subject device, the Frova Intubating Introducer is designed for establishing a pathway to introduce an endotracheal tube to a patient's airway. The intubation introducer is an 8 French, 35 cm long, single lumen catheter printed with incremental markings on the external surface. The introducer is made of radiopaque polyurethane and features a blunt and open distal tip with two sideports located on opposite sides of the

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distal tip. The introducer is compatible with an endotracheal tube with an inner diameter of 3.0 mm or larger.

The subject device intubation introducer is also preloaded with a stiffening stylet to provide extra stiffness to the introducer while it is being advanced into the patient's trachea. The stainless-steel stiffening stylet has an outer diameter of 0.051 inches and a length of 31 cm. A polyamide obturator hub is bonded to the stylet.

The subject device set also provides two Rapi-Fit adapters (one with a 15 mm connector, and one with a Luer lock connector) for ventilation when the oxygen requirement of a patient is high and the endotracheal tube is not in the trachea of the patient. The 15 mm Rapi-Fit adapter is intended for attachment to traditional ventilator sources that are low pressure sources, or so-called continuous positive airway pressure (CPAP) ventilators. The Luer Lock Rapi-Fit adapter is intended for attachment to a high-pressure jet ventilation oxygen source, and is compatible with a variable connector or the standard Luer fitting of an oxygen tube which is connected to an oxygen source.

Indication for Use:

The Frova Intubating Introducer is intended to facilitate endotracheal intubation in adult and pediatric patients where visualization of the glottis is inadequate.

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.

Comparison to Predicate:

The subject device is substantially equivalent to the predicate device in that they have the same fundamental design and intended use. Both are tubular devices with similar tip configuration and are intended for transient use to guide an endotracheal tube into the correct position within the trachea while providing continuous air flow. Furthermore, they have the same method of operation. The substantial equivalence comparison with the predicate device is provided in Table 1.

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Table 1: Substantial Equivalence Comparison Table

	Predicate Device	Subject Device
	William Cook Europe Aps Frova Intubating Introducer (K161813)	**Frova Intubating Introducer**
Regulation	21 CFR 868.5730	IDENTICAL TO PREDICATE
Product Code	BTR	IDENTICAL TO PREDICATE
Classification	II	IDENTICAL TO PREDICATE
Indication for Use	To facilitate endotracheal intubation in patients when visualization of the glottis is inadequate. The 14 French catheter introducer has been designed for placement of a single lumen endotracheal tube whose inner diameter is 6 mm or larger.	To facilitate endotracheal intubation in adult and pediatric patients where visualization of the glottis is inadequate. 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.
One-time use	Yes	IDENTICAL TO PREDICATE
Catheter insertion method	Orally or nasally into trachea	IDENTICAL TO PREDICATE
Catheter distal shape	Coude tip	IDENTICAL TO PREDICATE
Adapters available for oxygenation	1 15 mm adapter 1 Luer lock adapter	IDENTICAL TO PREDICATE
Catheter depth marking	Yes	IDENTICAL TO PREDICATE
Catheter distal tip sideport	2 sideports	IDENTICAL TO PREDICATE
Catheter outer diameter	14 Fr	8 Fr
Catheter length	70 cm	35 cm
Inner diameter of compatible endotracheal tube	≥ 6.0 mm	≥ 3.0 mm
Catheter distal end	Closed tip	Open endhole
Catheter material	Polyethylene	Polyurethane
Accessory set component	1 15 mm adapter 1 Luer lock adapter 1 stiffening stylet	IDENTICAL TO PREDICATE
Sterilization method	Ethylene Oxide	IDENTICAL TO PREDICATE
Packaging	Sealed Tyvek® peel-open pouch	IDENTICAL TO PREDICATE

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The differences in Indication for Use statement between the predicate and subject device do not raise different questions of safety or effectiveness because:

- **Size of compatible endotracheal tubes:** The predicate introducer is 14 French in outer diameter and is designed for placement of a single lumen endotracheal tube whose inner diameter is 6 mm or larger. The subject device introducer is 8 French in outer diameter and is designed for placement of a single lumen endotracheal tube whose inner diameter is 3 mm or larger. A validation study using a child training manikin was conducted and the results demonstrate that the subject device introducer was compatible with an endotracheal tube with an inner diameter of 3.0 mm and 3.5 mm.
- **Patient population:** The predicate device does not specify patient population, while the subject device is indicated for adult and pediatric patients. Endotracheal tubes are critical in establishing and maintaining a patient airway and are used in both adult and pediatric patients. It is common in clinical practice to use relatively small intubation catheters in pediatric patients because they generally require a smaller endotracheal tube. The subject device is within this dimensional range and has similar recommended compatible ET tube size ranges for pediatric use. In addition, a validation study using a child training manikin was conducted and the results demonstrate that the subject device introducer was compatible with an endotracheal tube with an inner diameter of 3.0 mm and 3.5 mm. Furthermore, a 3-mm endotracheal tube can be used in pediatric patients with a minimum weight of 1 kg. Therefore, it is appropriate to recommend the subject device to be used in pediatric patients overall as well as adult patients.

Technological Characteristics:

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

- Catheter separation force with Rapi-Fit adapter – the separation force between the catheter and the adapter shall be greater than that of the catheter tensile force requirement (15 N). The acceptance criterion was met.
- Catheter shaft tensile strength – the peak load of specified catheter shaft section shall be greater than or equal to 15 N. The acceptance criterion was met.

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- Catheter sideport tensile strength – the peak load of specified catheter shaft section shall be greater than or equal to 15 N. The acceptance criterion was met.
- Catheter shaft kink radius – the test articles shall pass the acceptance criteria as specified in ISO 5361. The acceptance criteria were met.
- Catheter shaft radiopacity – the radiopacity of the catheter shaft shall fall along the gradient of an aluminum X-ray step wedge gauge. The acceptance criterion was met.
- Stiffening stylet hub-to-shaft tensile – the peak load shall be greater than or equal to 15 N. The acceptance criterion was met.
- Design validation for pediatric use of device in intubation – airway training manikins that resemble appropriate patient anatomy of different sub-groups were used to demonstrate that the Frova Intubation Introducer meets the user needs and intended use for pediatric patients to assist intubation during difficult airway management procedures, when properly following the IFU. The acceptance criteria were met.
- Design validation for high pressure oxygenation insufflation during breathing simulator – 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.
- Biocompatibility testing – Per ISO 10993-1 and FDA guidance, testing for cytotoxicity, sensitization, intracutaneous irritation, acute systemic toxicity, material-mediated pyrogenicity, volatile organic compound testing, and particulate matter testing were performed to ensure the biocompatibility of the subject device.
- Acute performance evaluation on catheter via animal study – the catheter shall perform as intended in simulated clinical use. The acceptance criteria were met.

The results of these tests show that the subject device meets the design input requirements based on the intended use and support the conclusion that the subject device does not raise different questions of safety or effectiveness and is substantially equivalent to the predicate device.