DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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May 19, 2017

William Cook Europe ApS
Henriette Christiansen
Director of Regulatory Affairs
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Denmark

Re: K161813
Trade/Device Name: Frova Intubating Introducer
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: Class II
Product Code: BTR
Dated: April 19, 2017
Received: April 21, 2017

Dear Henriette Christiansen:

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,

Michael J. Ryan -S

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

11.0 INDICATIONS FOR USE

INDICATIONS FOR USE

510(k) Number (if known): K161813

Device Name: Frova Intubating Introducer

Indications for Use:

The Frova Intubating Introducer is intended to facilitate endotracheal intubation in patients where the visualization of the glottis in inadequate. The 14 French catheter has been designed for placement of a single lumen endotracheal tube whose inner diameter is 6 mm or larger.

Prescription Use ____X__	AND/OR	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

12.0 510(k) SUMMARY

Frova Intubating Introducer
21 CFR 807.92
Date Prepared: May 17, 2017

Submitted By:

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Device Information:

Trade Name:	Frova Intubating Introducer
Common Name:	Intubating Introducer
Classification Name:	Tube, Tracheal (W/Wo Connector)
Regulation:	21 CFR 868.5730
Product Code:	BTR

Predicate Devices:

The predicate is the Endotracheal Tube Exchanging Guide from Sheridan Catheter Corp. (K862347) used to facilitate airway management, by assisting in placement of an endotracheal tube while maintaining airflow.

Device Description:

The Frova Intubating Introducer is a 14 French, 70 cm long radiopaque catheter introducer with centimeter markings and a blunt, curved tip that can be passed blindly into the trachea, when visualization of the glottis is inadequate and only visualization of the epiglottis can be confirmed by laryngoscopy. The catheter introducer has a tubular design with two distal sideports to ensure adequate airflow. It can be supplied with or without a stiffening stylet and/or two Rapi-Fit adapters for connection to a ventilator device. Pressure and flow specifications for the device when used for oxygenation are as follows: mean delivered minute volume is 8.6 L/min and mean measured average maximum airway pressure is 12.1 cm H_2O (when input pressure is set to 50 psi, lung compliance is 100 mL/cm H_2O, and resistance is 3 cm H_2O/L/s). Incremental centimeter markings are placed on the shaft of the catheter introducer, with the first measurement marking designating 10 centimeters from the distal tip. The centimeter marks along the catheter shaft facilitate accurate depth placement of the catheter introducer into the airway.

The stiffening stylet is only provided with the catalogue number C-CAE-14.0-70-FII. The stiffening stylet is 10 cm shorter than the catheter introducer and provides columnar stiffness to the catheter introducer when needed. The Rapi-Fit adapters, comprised of a 15 mm connector and a Luer Lock connector, are only provided with the catalog numbers C-CAE-14.0-70-FI and C-CAE-14.0-70-FII.

Catalogue numbers C-CAE-14.0-70-FIC and C-CAE-14.0-70-FIC-SPOPS consist of the catheter introducer only. The C-CAE-14.0-70-FIC is supplied as a box of ten catheter introducers. The C-CAE-14.0-70-FIC-SPOPS is supplied in single units in a Tyvek peel-pouch package for easy transportation during special operations. The catheter introducer is curved in the middle to fit in a coat pocket or back-pack.

Intended Use:

The Frova Intubating Introducer is intended to facilitate endotracheal intubation in patients where the visualization of the glottis in inadequate. The 14 French catheter has been designed for placement of a single lumen endotracheal tube whose inner diameter is 6 mm or larger.

Comparison to Predicates:

The Frova Intubating Introducer and the predicate device, the Sheridan Endotracheal Tube Exchanging Guide, are substantially equivalent in that these devices have similar design and indications for use. Both are tubular devices of similar size and length and are intended for transient use to guide an endotracheal tube into its correct position within the trachea while providing continuous air flow. Additionally, the Frova Intubating Introducer is similar in technological characteristics, materials, and methods of construction to the Sheridan Endotracheal Tube Exchanging Guide indicated for respiratory use.

Technological Characteristics:

The Frova Intubating Introducer was subjected to the following tests to assure design and performance under the specified testing parameters:

Time Zero Testing

- Tensile strength, catheter introducer - The minimum tensile force must be larger than or equal to 15 N in accordance with EN/ISO 10555-1:2013. The acceptance criterion was met.
- Tensile strength, stiffening stylet - The minimum tensile force must be larger than or equal to 15 N in accordance with EN/ISO 10555-1:2013. The acceptance criterion was met.
- Tensile strength, catheter introducer/Rapi-Fit adapter connection - The minimum tensile force must be larger than or equal to 15 N in accordance with EN/ISO 10555-1:2013. The acceptance criterion was met.
- Kink radius, catheter introducer - The catheter introducer must not kink when tested at a 40 mm Radius of Curvature according to the test method described in Annex H of ISO 5361:2012. The acceptance criterion was met.

- Unscrewing torque, Luer Lock - When the fitting is tested in accordance with ISO 594-2, Section 5.5, the female Luer connection shall remain attached to the reference fitting. The acceptance criterion was met.
- Resistance to overriding, Luer Lock - When the fitting is tested in accordance with ISO 594-2, Section 5. 7, the reference fitting shall not override the threads of the conical fitting. The acceptance criterion was met.
- Separation Force, Luer Lock - When the fitting is tested in accordance with ISO 594-2, Section 5.4, it shall remain attached to the reference fitting. The acceptance criterion was met.
- Compliance verification, 15mm adapter - When the fitting is tested in accordance with ISO 5356-1:2015, Section 3.1.2, the leading edge of the 15 mm Rapi-Fit adapter shall lie between the minimum and maximum diameter step gauges. The acceptance criteria were met.
- Simulated Use - Each test article shall receive a rating of 2 or 3 on 3-point scale for each performance parameter. The acceptance criterion was met.
- Oxygenation - A characterization study was performed to 1) establish objective evidence that the introducer catheter is able to insufflate oxygen under a specified pressure, 2) characterize the delivered minute volume through the introducer catheter during simulated high pressure oxygenation insufflation, and 3) establish objective evidence that the introducer catheter may successfully couple with the Luer Lock Rapi-Fit adapter during simulated clinical use.
- Transportation - Testing was divided into three parts:
    - Part 1 visual inspection test of the shipping/product box. Damages are accepted on the Shipping boxes, as long as the product boxes are without holes/loose pieces or damages due to e.g. humidity etch. Small visible damages as pressure marks are allowed on the product boxes, as long as the sterile barrier and the Frova catheter is intact.
    - Part 2 inspection of sterile barrier (bubble leak/dye test if applicable). No breaches in the sterile barrier must be seen when the entire seal area is inspected. No visual tears or pinholes must be seen.
    - Part 3 inspection of device integrity after transportation. Catheter introducer shall have a curved tip after simulated shipping test. No kinks or damages must be found/seen on the catheter introducer.

      Additional acceptance criteria for C-CAE-14.0-70-FII and C-CAE-14.0-70-FII: The adapter shall be able to be attached and locked to the catheter introducer according to the IFU and not be able to be taken off by pulling in the adapter when locked. The adapter shall be able to be removed from the catheter introducer according to the IFU.

  All acceptance criteria were met.
- Ink adherence and radiopacity - Testing was performed as simulated use testing in domestic swine, following which each test article was quantitatively evaluated on a 3-point scale with respect to legibility of the printed markings and radiopacity.

Each test article shall receive a rating of 2 or 3 to pass. All acceptance criteria were met.

Accelerated Age Testing (equivalent of three years real time aging)

- Tensile strength, catheter introducer - The minimum tensile force must be larger than or equal to 15 N in accordance with EN/ISO 10555-1:2013. The acceptance criterion was met.
- Tensile strength, stiffening stylet - The minimum tensile force must be larger than or equal to 15 N in accordance with EN/ISO 10555-1:2013. The acceptance criterion was met.
- Tensile strength, catheter introducer/Rapi-Fit adapter connection - The minimum tensile force must be larger than or equal to 15 N in accordance with EN/ISO 10555-1:2013. The acceptance criterion was met.
- Kink radius, catheter introducer - The catheter introducer must not kink when tested at a 40 mm Radius of Curvature according to the test method described in Annex H of ISO 5361:2012. The acceptance criterion was met.
- Unscrewing torque, Luer Lock - When the fitting is tested in accordance with ISO 594-2, Section 5.5, the female Luer connection shall remain attached to the reference fitting. The acceptance criterion was met.
- Resistance to overriding, Luer Lock - When the fitting is tested in accordance with ISO 594-2, Section 5. 7, the reference fitting shall not override the threads of the conical fitting. The acceptance criterion was met.
- Separation Force, Luer Lock - When the fitting is tested in accordance with ISO 594-2, Section 5.4, it shall remain attached to the reference fitting. The acceptance criterion was met.
- Compliance verification, 15mm adapter - When the fitting is tested in accordance with ISO 5356-1:2015, Section 3.1.2, the leading edge of the 15 mm Rapi-Fit adapter shall lie between the minimum and maximum diameter step gauges. The acceptance criteria were met.
- Sterile barrier and dimensional verification (accelerated aging) - Testing was divided into three parts. Part 1 visual inspection test of the Tyvek pouch in accordance with ASTM F1886-16, part 2 bubble leak test of Tyvek pouch in accordance with ASTM F2096-11 (dye test if applicable in accordance with F1929-15) and part 3 inspection of device integrity after accelerated aging. The acceptance criteria were as follows:
    - The sterile barrier shall be intact after accelerated ageing (verified with a bubble leak test in accordance with ASTM F2096-11, dye test according to ASTM F1929-15)
    - The product shall appear intact as per visual inspection
    - The angle of the tip of the catheter must not exceed the tolerances according to the applicable drawing

- The length of the catheter must be 70 cm ± 3mm according to the applicable drawing and Incoming Quality Control Instruction
- The ID and OD of the catheter must be according to the applicable Incoming Quality Control Instruction:
    - ID: 3.124 mm ± 0.05 mm.
    - OD: 4.674 mm ± 0.05 mm
- The print must be clear and visible according to the applicable manufacturing instructions and within the tolerances specified on the applicable drawing
- The Rapi-Fit adapters shall be able to be attached and locked to the catheter introducer according to the IFU.

All acceptance criteria were met.

- Ink adherence and radiopacity - Testing was performed as simulated use testing in domestic swine, following which each test article was quantitatively evaluated on a 3-point scale with respect to legibility of the printed markings and radiopacity. Each test article shall receive a rating of 2 or 3 to pass. All acceptance criteria were met.

Biocompatibility

- Biocompatibility testing was performed in accordance with ISO 10993-1:2009 and FDA guidance on Use of International Standard ISO 10993-1. Testing for cytotoxicity, sensitization, intracutaneous irritation, acute systemic toxicity and material mediated pyrogenicity was performed to ensure the biocompatibility of the devices. All biocompatibility tests showed passed results.
- Testing for volatile organic compounds was performed on the dry gas pathway of the device. No VOCs were detected greater than the quantification limits set for the specific group of compounds that were assayed and no additional VOCs were detected. The subsequent risk assessment determined the likelihood of a toxic effect from VOCs from the device negligible.
- Characterization of particulate matter emission was also performed on the dry gas pathway of the device. Results demonstrate that the Frova Intubating Introducer presents a clinically insignificant health risk to patients on which the device is used.

Conclusion:

The results of the testing provide reasonable assurance that the Frova Intubating Introducer has been designed such that it will function as intended. The devices do not raise different questions of safety or effectiveness as compared to the predicate devices.