June 11, 2025

William Cook Europe Aps
Janne Soerensen
Senior Specialist, Regulatory Affairs
Sandet 6
Bjaeverskov, 4632
Denmark

Re: K251499
Trade/Device Name: Frova Intubating Introducer (C-CAE-14.0-70-FII); Frova Intubating Introducer (C-CAE-14.0-70-FI); Frova Intubating Introducer (C-CAE-14.0-70-FIC); Frova Intubating Introducer (C-CAE-14.0-70-FIC-SPOPS)
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: Class II
Product Code: BTR
Dated: May 8, 2025
Received: May 15, 2025

Dear Janne Soerensen:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bradley Q. Quinn -S

Bradley Quinn
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251499

Please provide the device trade name(s).

Frova Intubating Introducer (C-CAE-14.0-70-FII);
Frova Intubating Introducer (C-CAE-14.0-70-FI);
Frova Intubating Introducer (C-CAE-14.0-70-FIC);
Frova Intubating Introducer (C-CAE-14.0-70-FIC-SPOPS)

Please provide your Indications for Use below.

The Frova Intubating Introducer is indicated to facilitate endotracheal intubation in patients where visualization of the glottis is inadequate e.g., as in grade II and III Cormack-Lehane views. This indication applies for introduction of a single lumen endotracheal tube with an inner diameter of 6 mm or larger. The Frova Intubating Introducer is also designed for transient oxygenation or jet ventilation in combination with 14 Fr compatible Rapi-Fit Adapters (15 mm and female Luer lock connector). The Rapi-Fit Adapters should only be used when oxygen requirements are high.

Please select the types of uses (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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510(k) Summary
Frova Intubating Introducer

Date prepared: June 11, 2025

Submitted By

Applicant:	William Cook Europe ApS
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Device Information

Trade Name:	Frova Intubating Introducer
Common Name:	Frova Introducer
Classification Name:	Tracheal tube
Regulation:	21 CFR 868.5730
Product Code:	BTR
Catalog Numbers:	C-CAE-14.0-70-FII C-CAE-14.0-70-FI C-CAE-14.0-70-FIC C-CAE-14.0-70-FIC-SPOPS

Predicate Device

The subject Frova Intubating Introducer is substantially equivalent to the predicate Frova Intubating Introducer, which was initially cleared for commercial distribution in US in 2017 under K161813.

Device Description

The Frova Intubating Introducer is a 14 French, 70 cm long radiopaque introducer with centimeter markings and a blunt, curved tip that can be passed into the trachea. The introducer has a through lumen design with two distal sideports to ensure adequate airflow. The Frova Intubating Introducer can be supplied with a stiffening stylet and two Rapi-Fit® Adapters for connection to an oxygen source. The Frova Intubating Introducer is designed to facilitate airway intubation and allows for transient oxygenation and/or jet ventilation during the initial intubation.

The Rapi-Fit Adapter with a 15 mm connector is intended for use with a 14 Fr Frova Intubating Introducer for connection to an oxygen source to facilitate transient oxygenation during intubation.

The Rapi-Fit Adapter with a female Luer lock connector is intended for use with a 14 Fr Frova Intubating Introducer for connection to an oxygen source to facilitate transient oxygenation or jet ventilation during intubation.

The stiffening stylet is intended to add rigidity to the proximal and middle sections of the introducer, while the distal portion remains flexible.

The different configurations of the Frova Intubating Introducer are supplied sterile and are for single use only.

Intended Use
The Frova Intubating Introducer is intended to facilitate endotracheal intubation in patients where the visualization of the glottis is inadequate. The Rapi-Fit Adapters are intended to connect the Frova Intubating Introducer to an oxygen source.

Indications for Use
The Frova Intubating Introducer is indicated to facilitate endotracheal intubation in patients where visualization of the glottis is inadequate e.g., as in grade II and III Cormack-Lehane views. This indication applies for introduction of a single lumen endotracheal tube with an inner diameter of 6 mm or larger.
The Frova Intubating Introducer is also designed for transient oxygenation or jet ventilation in combination with 14 Fr compatible Rapi-Fit Adapters (15 mm and female Luer lock connector). The Rapi-Fit Adapters should only be used when oxygen requirements are high.

Comparison to Predicates
The subject device is substantially equivalent to the predicate Frova Intubating Introducer cleared under K161813. The intended use and the design and technological characteristics of the subject device are identical to the predicate device. The changes proposed in this submission are to the labeling of the devices; including the product label and multiple sections of the Instructions for Use. The proposed changes result from revisions to the labeling during certification to the EU Medical Device Regulation (Regulation (EU) 2017/745). The same changes are proposed herein to support a harmonized approach to labeling of the Frova Intubating Introducer across regions. The subject device is otherwise identical to the predicate device in all aspects, including materials, design, manufacturing processes, packaging and sterilization.

Technological Characteristics
The technological characterics remain the same as for the predicate device.
The introducer is a 14 French, 70 cm long introducer made from radiopaque polyethylene with centimeter markings and a blunt, curved tip. The introducer has a through lumen design with two distal sideports to ensure adequate airflow. Two adapters and one stiffening stylet are available as accessories. The introducer is compatible with single lumen endotracheal tubes with an inner diameter of 6 mm or larger. The device is supplied as single use in a Tyvek® peel pouch, sterilized by ethylene oxide gas.

Performance Testing
No changes to the design, manufacturing, sterilization, or principles of operation have been introduced with the subject device. Therefore, no performance testing was warranted in support of this 510(k) premarket notification.

Conclusion

The subject device is substantially equivalent to the predicate Frova Intubating Introducer cleared under K161813. The intended use and the design and technological characteristics of the subject device are identical to the predicate device. The changes proposed in this submission are to the labeling of the devices in an effort to gain global harmonization of the labeling across regions.