

**K251499 Frova Intubating Introducer (C-CAE-14.0-70-FII)**Jun 11, 2025  
27 days to decisionK251499 · Product code: **BTR** · Anesthesiology  
Source: <https://www.510kdatabase.net/k251499/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Special  |
| Device classification | Tube, Tracheal (w/wo Connector) (BTR)  |
| Date received         | May 15, 2025   |
| Decision date         | Jun 11, 2025   |
| Days to decision      | 27 days  |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Summary  |
| Other names           | 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) |

**APPLICANT**

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|----------------|---|
| Company        | <b>William Cook Europe Aps</b>          |
| Location       | Bjaeverskov, DK                         |
| Contact        | Mie Dyrholm                             |
| 510(k) history | 18 submissions · 18 cleared · 2007-2025 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251499/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 14, 2026