

**K250635 FEops HEARTguide Simulation Application**Nov 25, 2025  
267 days to decisionK250635 · Product code: **QQI** · Cardiovascular  
Source: <https://www.510kdatabase.net/k250635/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Cardiovascular Implant Simulation Software Device (QQI)
Date received	Mar 3, 2025
Decision date	Nov 25, 2025
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Feops NV</b>
Location	Gent-Zwijnaarde, BE
Contact	Franky Dubois
510(k) history	4 submissions · 3 cleared · 2021-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250635/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026