

**K223855 FEops HEARTguide™, FEops HEARTguide™
ALPACA**Jun 6, 2023
165 days to decisionK223855 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k223855/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Dec 23, 2022
Decision date	Jun 6, 2023
Days to decision	165 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Feops NV
Location	Gent-Zwijnaarde, BE
Contact	Peter Mortier
510(k) history	4 submissions · 3 cleared · 2021-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223855/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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