

K260885 VERAFFEYE Imaging and Guidance System (VF-VIS-002)Jun 15, 2026
90 days to decision

K260885 · Cardiovascular

Source: <https://www.510kdatabase.net/k260885/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Date received	Mar 17, 2026
Decision date	Jun 15, 2026
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Luma Vision Limited
Location	Dublin, IE
Contact	Marta Walker
510(k) history	2 submissions · 2 cleared · 2025-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k260885/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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