

**K242893 VERAFFEYE System VERAFFEYE Imaging Catheter & VERAFFEYE Imaging System**Mar 24, 2025  
182 days to decisionK242893 · Product code: **OBJ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k242893/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Ultrasound, Intravascular (OBJ)
Date received	Sep 23, 2024
Decision date	Mar 24, 2025
Days to decision	182 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Luma Vision Limited</b>
Location	Dublin, IE
Contact	Marta Walker
510(k) history	1 submissions · 1 cleared · 2025-2025

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242893/> 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