FDA 510(k) Premarket Notification

CLEARED

K242893 VERAFEYE System VERAFEYE Imaging Catheter & VERAFEYE Imaging System

Mar 24, 2025
182 days to decision

K242893 · Product code: **OBJ** · Cardiovascular
Source: https://www.510kdatabase.net/k242893/

SUBMISSION DETAILS

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

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