

K261849 VERAFEYE Imaging Catheter (VF-VIC-002)

Jul 24, 2026  
51 days to decision

K261849 · Product code: **OBJ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k261849/>

SUBMISSION DETAILS

|                       |                                           |
|-----------------------|-------------------------------------------|
| Decision              | Substantially Equivalent (Cleared)        |
| Submission type       | Special                                   |
| Device classification | Catheter, Ultrasound, Intravascular (OBJ) |
| Date received         | Jun 3, 2026                               |
| Decision date         | Jul 24, 2026                              |
| Days to decision      | 51 days                                   |
| Third-party review    | No                                        |
| Summary / Statement   | Summary                                   |

APPLICANT

|                |                                       |
|----------------|---------------------------------------|
| Company        | Luma Vision Limited                   |
| Location       | Dublin, IE                            |
| Contact        | Marta Walker                          |
| 510(k) history | 3 submissions · 3 cleared · 2025-2026 |