

K230934 ViewFlex™ Eco Reprocessed ICE CatheterMay 3, 2023
30 days to decisionK230934 · Product code: **OWQ** · Cardiovascular
Source: <https://www.510kdatabase.net/k230934/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Reprocessed Intravascular Ultrasound Catheter (OWQ) |
| Date received | Apr 3, 2023 |
| Decision date | May 3, 2023 |
| Days to decision | 30 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Abbott Medical |
| Location | S,Mta Clara, CA, US |
| Contact | Quynh Phuong Le |
| Website | https://www.abbott.com |
| 510(k) history | 57 submissions · 57 cleared · 2019-2026 |

Abbott Medical is a global healthcare technology company headquartered in Santa Clara, US. The company specializes in life-changing medical devices and diagnostic solutions across multiple therapeutic areas. Abbott Medical maintains a strong FDA 510(k) regulatory record with FDA 510(k) clearances from total submissions. The company's primary focus is Cardiovascular devices, which represent 94% of its submission portfolio. Clearances span from 2019 to 2026, with recent activity demonstrating continued innovation in interventional cardiology and electrophysiology systems. R...

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Device record: <https://www.510kdatabase.net/k230934/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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