

K231621 Reprocessed ViewFlex Xtra ICE Catheter (D087031)Jul 25, 2023
53 days to decisionK231621 · Product code: **OWQ** · CardiovascularSource: <https://www.510kdatabase.net/k231621/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Reprocessed Intravascular Ultrasound Catheter (OWQ)
Date received	Jun 2, 2023
Decision date	Jul 25, 2023
Days to decision	53 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Stryker Sustainability Solutions
Location	Tempe, AZ, US
Contact	Mia Brown
510(k) history	31 submissions · 31 cleared · 2011-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231621/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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