

**K223077 ViewFlex Xtra ICE Catheter**Dec 7, 2022  
68 days to decisionK223077 · Product code: **OBJ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k223077/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Ultrasound, Intravascular (OBJ)
Date received	Sep 30, 2022
Decision date	Dec 7, 2022
Days to decision	68 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Irvine Biomedical, A St. Jude Medical Company</b>
Location	Irvine, CA, US
Contact	Suzanne Pekarna
510(k) history	1 submissions · 1 cleared · 2022-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k223077/> 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 26, 2026