

K133853 VIEWFLEX XTRA ICE CATHETERMay 19, 2014
151 days to decisionK133853 · Product code: **OBJ** · Cardiovascular
Source: <https://www.510kdatabase.net/k133853/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Ultrasound, Intravascular (OBJ)
Date received	Dec 19, 2013
Decision date	May 19, 2014
Days to decision	151 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Irvine Biomedical, Inc., A St. Jude Medical Company
Location	Irvine, CA, US
Contact	JENNIFER CORREA
510(k) history	1 submissions · 1 cleared · 2014-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k133853/> Data sourced from FDA 510(k) public records (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. - Generated June 30, 2026