

K121273 VISIONS PV .035 DITITAL IVUS CATHETERSep 10, 2012
136 days to decisionK121273 · Product code: **OBJ** · CardiovascularSource: <https://www.510kdatabase.net/k121273/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Catheter, Ultrasound, Intravascular (OBJ)
Date received	Apr 27, 2012
Decision date	Sep 10, 2012
Days to decision	136 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Volcano Corporation
Location	Rancho Cordova,, CA, US
Contact	MARILYN POURAZAR
510(k) history	55 submissions · 55 cleared · 2005-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k121273/> 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 May 14, 2026