

**K160583 REFINITY Rotational IVUS Catheter, REFINITY
Rotational IVUS Catheter, Short Tip**Oct 26, 2016
239 days to decisionK160583 · Product code: **OBJ** · Cardiovascular
Source: <https://www.510kdatabase.net/k160583/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Ultrasound, Intravascular (OBJ)
Date received	Mar 1, 2016
Decision date	Oct 26, 2016
Days to decision	239 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k160583/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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