

K113486 VOLCANO S5I INTRAVASCULAR ULTRACOUND IMAGING AND PRESSURE SYSTEM

Jan 27, 2012
65 days to decision

K113486 · Product code: IYO · Radiology
Source: <https://www.510kdatabase.net/k113486/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Nov 23, 2011
Decision date	Jan 27, 2012
Days to decision	65 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k113486/> 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