

K122878 HD-IVUS ULTRASOUND IMAGING SYSTEMJan 11, 2013
114 days to decisionK122878 · Product code: **OBJ** · Cardiovascular
Source: <https://www.510kdatabase.net/k122878/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Ultrasound, Intravascular (OBJ)
Date received	Sep 19, 2012
Decision date	Jan 11, 2013
Days to decision	114 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Silicon Vally Medical Instruments, Inc.
Location	Fremont, CA, US
Contact	RICHARD E ANDERSON
510(k) history	3 submissions · 3 cleared · 2011-2013

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