

K112997 HD-IVUS ULTRASOUND IMAGING SYSTEMDec 17, 2011
71 days to decisionK112997 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k112997/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Oct 7, 2011
Decision date	Dec 17, 2011
Days to decision	71 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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