

K153421 HI VISION ASCENDUS, HV ASCENDUS, ASCENDUSJan 21, 2016
57 days to decisionK153421 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k153421/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Nov 25, 2015
Decision date	Jan 21, 2016
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hitachi Aloka Medical America, Inc.
Location	Wallingford, CT, US
Contact	ANGELA VAN ARSDALE
510(k) history	3 submissions · 3 cleared · 2014-2016

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