

**K161439 E-CUBE 11**Sep 21, 2016  
120 days to decisionK161439 · Product code: **IYN** · Radiology  
Source: <https://www.510kdatabase.net/k161439/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	May 24, 2016
Decision date	Sep 21, 2016
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Alpinion Medical Systems Co., Ltd.</b>
Location	Kirkland, WA, US
Contact	DONGHWAN KIM
510(k) history	26 submissions · 26 cleared · 2011-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161439/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 16, 2026