

**K200450 X-Cube 70**Jul 10, 2020  
137 days to decisionK200450 · Product code: **IYN** · Radiology  
Source: <https://www.510kdatabase.net/k200450/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Feb 24, 2020
Decision date	Jul 10, 2020
Days to decision	137 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	Boyeon CHO
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/k200450/> 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 15, 2026