

**K213523 X-CUBE i8, X-CUBE i9**Jan 28, 2022  
86 days to decisionK213523 · Product code: IYN · Radiology  
Source: <https://www.510kdatabase.net/k213523/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Nov 3, 2021
Decision date	Jan 28, 2022
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	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/k213523/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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