

K223564 X-CUBE 50, X-CUBE 60Apr 17, 2023
139 days to decisionK223564 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k223564/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Nov 29, 2022
Decision date	Apr 17, 2023
Days to decision	139 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Alpinion Medical Systems Co., Ltd.
Location	Kirkland, WA, US
Contact	Boyeon CHO
510(k) history	26 submissions · 26 cleared · 2011-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223564/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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