

K211299 X-CUBE 70Aug 9, 2021
103 days to decisionK211299 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k211299/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Apr 28, 2021
Decision date	Aug 9, 2021
Days to decision	103 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/k211299/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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