

K221093 X-CUBE 70, X-CUBE 90Oct 14, 2022
184 days to decisionK221093 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k221093/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Apr 13, 2022
Decision date	Oct 14, 2022
Days to decision	184 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

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