

**K220857 X-CUBE 50, X-CUBE 60**Oct 13, 2022  
204 days to decisionK220857 · Product code: IYN · Radiology  
Source: <https://www.510kdatabase.net/k220857/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                |
| Submission type       | Traditional                                       |
| Device classification | System, Imaging, Pulsed Doppler, Ultrasonic (IYN) |
| Date received         | Mar 23, 2022                                      |
| Decision date         | Oct 13, 2022                                      |
| Days to decision      | 204 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/k220857/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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