

K172732 E-CUBE 8Dec 14, 2017
94 days to decisionK172732 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k172732/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Imaging, Pulsed Doppler, Ultrasonic (IYN) |
| Date received | Sep 11, 2017 |
| Decision date | Dec 14, 2017 |
| Days to decision | 94 days |
| Third-party review | 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/k172732/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 16, 2026