

# K213731 EFAI CARDIOSUITE SPECT Myocardial Perfusion Agile Workflows

May 31, 2022  
186 days to decisionK213731 · Product code: **KPS** · Radiology  
Source: <https://www.510kdatabase.net/k213731/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)           |
| Submission type       | Traditional                                  |
| Device classification | System, Tomography, Computed, Emission (KPS) |
| Date received         | Nov 26, 2021                                 |
| Decision date         | May 31, 2022                                 |
| Days to decision      | 186 days                                     |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Summary                                      |

**APPLICANT**

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|----------------|---|
| Company        | <b>Ever Fortune.Ai, Co., Ltd.</b>       |
| Location       | Taichung City, TW                       |
| Contact        | Cheng Ming-Fong                         |
| 510(k) history | 15 submissions · 15 cleared · 2021-2026 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213731/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 26, 2026