

**K253733 STAR Apollo™ Mapping System**Dec 19, 2025  
25 days to decisionK253733 · Product code: **DQK** · CardiovascularSource: <https://www.510kdatabase.net/k253733/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)       |
| Submission type       | Special                                  |
| Device classification | Computer, Diagnostic, Programmable (DQK) |
| Date received         | Nov 24, 2025                             |
| Decision date         | Dec 19, 2025                             |
| Days to decision      | 25 days                                  |
| Third-party review    | No                                       |
| Combination product   | No                                       |
| PCCP authorized       | No                                       |
| Summary / Statement   | Summary                                  |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Rhythm AI, Ltd.</b>                |
| Location       | London, GB                            |
| Contact        | D&apos;Abate Linda                    |
| 510(k) history | 2 submissions · 2 cleared · 2024-2025 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k253733/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 13, 2026