

**K243484 PM2+ System and SmartPICC Stylet**May 29, 2025  
202 days to decisionK243484 · Product code: **LJS** · Cardiovascular  
Source: <https://www.510kdatabase.net/k243484/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Traditional  |
| Device classification | Catheter, Intravascular, Therapeutic, Long-term Greater Than 30 Days (LJS) |
| Date received         | Nov 8, 2024  |
| Decision date         | May 29, 2025   |
| Days to decision      | 202 days   |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Piccolo Medical, Inc.</b>          |
| Location       | San Francisco, CA, US                 |
| Contact        | Augustus Shanahan                     |
| 510(k) history | 4 submissions · 4 cleared · 2021-2025 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243484/> 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