

K240486 PM2 System and ECGuide ConnectorSep 8, 2024
201 days to decisionK240486 · Product code: **LJS** · Cardiovascular
Source: <https://www.510kdatabase.net/k240486/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Therapeutic, Long-term Greater Than 30 Days (LJS)
Date received	Feb 20, 2024
Decision date	Sep 8, 2024
Days to decision	201 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240486/> 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 13, 2026