FDA 510(k) Premarket Notification

CLEARED

K252792 PM2™ System with ECGuide™ Connector

Nov 17, 2025
76 days to decision

K252792 · Product code: **LJS** · Cardiovascular
Source: https://www.510kdatabase.net/k252792/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Intravascular, Therapeutic, Long-term Greater Than 30 Days (LJS)
Date received	Sep 2, 2025
Decision date	Nov 17, 2025
Days to decision	76 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

REGULATORY CONSULTANT

Consulting firm	**RQM+**
Contact	Alexia Haralambous

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov