FDA 510(k) Premarket Notification

K200037 Piccolo Medical SmartPICC System

CLEARED

Jan 22, 2021
380 days to decision

K200037 · Product code: **LJS** · Cardiovascular
Source: https://www.510kdatabase.net/k200037/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Therapeutic, Long-term Greater Than 30 Days (LJS)
Date received	Jan 8, 2020
Decision date	Jan 22, 2021
Days to decision	380 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	Alexey Salamini
510(k) history	4 submissions · 4 cleared · 2021-2025

REGULATORY CONSULTANT

Consulting firm	**Arina Consulting**
Contact	Allison Kumar

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k200037/ 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 25, 2026