FDA 510(k) Premarket Notification

K241781 Solo Pace Control

CLEARED

Jan 10, 2025
204 days to decision

K241781 · Product code: **DTE** · Cardiovascular
Source: https://www.510kdatabase.net/k241781/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pulse-generator, Pacemaker, External (DTE)
Date received	Jun 20, 2024
Decision date	Jan 10, 2025
Days to decision	204 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Solo Pace, Inc.**
Location	Petaluma, CA, US
Contact	David Daniels
510(k) history	2 submissions · 2 cleared · 2025-2026

REGULATORY CONSULTANT

Consulting firm	**Insight Medical Consulting, LLC**
Contact	Wanda Carpinella

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