

K241781 Solo Pace ControlJan 10, 2025
204 days to decisionK241781 · 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](https://accessdata.fda.gov)

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