FDA 510(k) Premarket Notification

CLEARED

K252204 prolaio eVO2peak Module (Version 1.0)

Dec 16, 2025
155 days to decision

K252204 · Product code: **PPW** · Cardiovascular
Source: https://www.510kdatabase.net/k252204/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Adjunctive Cardiovascular Status Indicator (PPW)
Date received	Jul 14, 2025
Decision date	Dec 16, 2025
Days to decision	155 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Prolaio, Inc.**
Location	Chicago, IL, US
Contact	George Allen Hides
510(k) history	1 submissions · 1 cleared · 2025-2025

CLINICAL EVIDENCE - NCT05678530

Observational, Non-Interventional Study Supporting Validation of VO2Max Estimation Methods Using Results in Patients Receiving Standard of Care Cardiopulmonary Exercise Tests (CPET)

Status	Recruiting - *No results published to ClinicalTrials.gov*
Enrollment	1000 patients (estimated)
Study sites	16 sites
Condition studied	Cardiopulmonary
Study type	Observational
Completion date	Mar 31, 2027
Sponsor	Prolaio (Industry)

Primary outcome

Collect development and validation data for a VO2Max (eVO2Max) machine learning algorithm and to evaluate the performance of the algorithm.

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05678530