

K254169 SmartSpectra Vital Signs Monitor 1.0Jun 18, 2026
177 days to decisionK254169 · Product code: **QME** · Cardiovascular
Source: <https://www.510kdatabase.net/k254169/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Software For Optical Camera-based Measurement Of Pulse Rate, Heart Rate, Breathing Rate, And/or Respiratory Rate (QME)
Date received	Dec 23, 2025
Decision date	Jun 18, 2026
Days to decision	177 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Presage Security, Inc. d/b/a Presage Technologies, Inc.
Location	Leesburg, VA, US
Contact	Michael Kenney
510(k) history	1 submissions · 1 cleared · 2026-2026

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