FDA 510(k) Premarket Notification

CLEARED

K260066 PanopticAI Vital Signs (1.6.1-22)

May 21, 2026
132 days to decision

K260066 · Product code: **QME** · Cardiovascular
Source: https://www.510kdatabase.net/k260066/

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	Jan 9, 2026
Decision date	May 21, 2026
Days to decision	132 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**PanopticAI technologies Limited**
Location	Hong Kong, HK
Contact	Nick Chin
510(k) history	2 submissions · 2 cleared · 2024-2026

REGULATORY CONSULTANT

Consulting firm	**Vee Care (Asia) Limited**
Contact	Evie Chen

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