FDA 510(k) Premarket Notification

K242876 Pulse Oximeter (PO2, PO2A, PO2B)

CLEARED

Feb 28, 2025
158 days to decision

K242876 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k242876/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Sep 23, 2024
Decision date	Feb 28, 2025
Days to decision	158 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen Viatom Technology Co., Ltd.**
Location	Shen Zhen, CN
Contact	Lynne Li
510(k) history	5 submissions · 5 cleared · 2019-2025

REGULATORY CONSULTANT

Consulting firm	**Irc**
Contact	Charles Mack

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