FDA 510(k) Premarket Notification

K250837 Pulse Oximeter

CLEARED

Sep 25, 2025
189 days to decision

K250837 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k250837/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Mar 20, 2025
Decision date	Sep 25, 2025
Days to decision	189 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shanghai Berry Electronic Tech Co., Ltd.**
Location	Shanghai, CN
Contact	Xu Yan
510(k) history	3 submissions · 3 cleared · 2015-2025

REGULATORY CONSULTANT

Consulting firm	**Shanghai Truthful Information Technology Co., Ltd.**
Contact	Boyle Wang

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