FDA 510(k) Premarket Notification

K251751 Spo2 Sensor CSS032D

CLEARED

Dec 19, 2025
193 days to decision

K251751 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k251751/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Jun 9, 2025
Decision date	Dec 19, 2025
Days to decision	193 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen Ykd Technology Co., Ltd.**
Location	Shenzhen, CN
Contact	Long Zhao
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**Feiying Drug & Medical Consulting Technical Service Group**
Contact	Youshan Gong

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