FDA 510(k) Premarket Notification

K231288 Vyvo

CLEARED

Mar 4, 2024
305 days to decision

K231288 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k231288/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	May 4, 2023
Decision date	Mar 4, 2024
Days to decision	305 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Vyvo Technology Corp.(Vt)**
Location	Miami, FL, US
Contact	Alfonso Cioffi
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	**Shenzhen Global Medical Technology Services Co., Ltd.**
Contact	Aileen Fu

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