FDA 510(k) Premarket Notification

K241086 Avidhrt Sense SpO2

CLEARED

May 9, 2025
385 days to decision

K241086 · Product code: **DQA** · Cardiovascular
Source: https://www.510kdatabase.net/k241086/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Apr 19, 2024
Decision date	May 9, 2025
Days to decision	385 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Avidhrt, Inc.**
Location	East Lansing, MI, US
Contact	Prabode Weebadde
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**Mdqr, LLC**
Contact	Raghavan Prabhu

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