FDA 510(k) Premarket Notification

K241152 InSee

CLEARED

Aug 21, 2025
482 days to decision

K241152 · Product code: **BWF** · Anesthesiology
Source: https://www.510kdatabase.net/k241152/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Therapeutic (incentive) (BWF)
Date received	Apr 26, 2024
Decision date	Aug 21, 2025
Days to decision	482 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Tidal Medical Technologies, LLC**
Location	San Francisco, CA, US
Contact	Mehdi Arani
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**Medicsense USA, LLC**
Contact	George Hattub

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