

K251133 AVEA disposable expiratory filter/water trap (11790)May 8, 2025
27 days to decisionK251133 · Product code: **CBK** · Anesthesiology
Source: <https://www.510kdatabase.net/k251133/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Facility Use (CBK)
Date received	Apr 11, 2025
Decision date	May 8, 2025
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Telesair, Inc.
Location	Irvine, CA, US
Contact	Don Lin
510(k) history	2 submissions · 2 cleared · 2023-2025

REGULATORY CONSULTANT

Consulting firm	ProMedic, LLC
Contact	Paul Dryden

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