

K201082 LTV2 Series VentilatorsNov 10, 2021
566 days to decisionK201082 · Product code: **CBK** · AnesthesiologySource: <https://www.510kdatabase.net/k201082/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Facility Use (CBK)
Date received	Apr 23, 2020
Decision date	Nov 10, 2021
Days to decision	566 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Vyair Medical, Inc.
Location	Helsinki, FI
Contact	Colleen Watson
510(k) history	9 submissions · 9 cleared · 2018-2024

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