

K202970 Ventway SparrowJan 29, 2021
121 days to decisionK202970 · Product code: **CBK** · Anesthesiology
Source: <https://www.510kdatabase.net/k202970/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Facility Use (CBK)
Date received	Sep 30, 2020
Decision date	Jan 29, 2021
Days to decision	121 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Inovytech Medical Solutions , Ltd.
Location	Hod Hasharon Tel-Aviv, IL
Contact	Dana Hofeller
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	C/O Promedic, LLC
Contact	Paul Dryden

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202970/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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