FDA 510(k) Premarket Notification

K183364 Bellavista

CLEARED

Sep 13, 2019
283 days to decision

K183364 · Product code: **CBK** · Anesthesiology
Source: https://www.510kdatabase.net/k183364/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Facility Use (CBK)
Date received	Dec 4, 2018
Decision date	Sep 13, 2019
Days to decision	283 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Imtmedical AG**
Location	Buchs Sg, CH
Contact	Beat Keller
510(k) history	2 submissions · 2 cleared · 2017-2019

REGULATORY CONSULTANT

Consulting firm	**Vyaire Medical**
Contact	Colleen Watson

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k183364/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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