FDA 510(k) Premarket Notification

K210384 CARESCAPE R860

CLEARED

Nov 4, 2021
268 days to decision

K210384 · Product code: **CBK** · Anesthesiology
Source: https://www.510kdatabase.net/k210384/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Facility Use (CBK)
Date received	Feb 9, 2021
Decision date	Nov 4, 2021
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Datex-Ohmeda, Inc.**
Location	Madison, WI, US
Contact	Trishia Mercier
510(k) history	60 submissions · 60 cleared · 1998-2025