FDA 510(k) Premarket Notification

K213098 Panther 5

CLEARED

Jul 20, 2023
664 days to decision

K213098 · Product code: **CBK** · Anesthesiology
Source: https://www.510kdatabase.net/k213098/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Facility Use (CBK)
Date received	Sep 24, 2021
Decision date	Jul 20, 2023
Days to decision	664 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Origin Medical Devices**
Location	Newport Beach, CA, US
Contact	Brent Chamblee
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Arazy Group Consultants, Inc.**
Contact	Ray Kelly

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