FDA 510(k) Premarket Notification

K121891 NEWPORT AURA VENTILATOR

CLEARED

Nov 9, 2012
133 days to decision

K121891 · Product code: **CBK** · Anesthesiology
Source: https://www.510kdatabase.net/k121891/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Facility Use (CBK)
Date received	Jun 29, 2012
Decision date	Nov 9, 2012
Days to decision	133 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Newport Medical Instruments, Inc.**
Location	Mchenry, IL, US
Contact	TOM COLONNA
510(k) history	22 submissions · 19 cleared · 1982-2012