FDA 510(k) Premarket Notification

K081330 CAREVENT PAR (PUBLIC ACCESS RESUSCITATOR)

CLEARED

Mar 6, 2009
298 days to decision

K081330 · Product code: **BTL** · Anesthesiology
Source: https://www.510kdatabase.net/k081330/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Emergency, Powered (resuscitator) (BTL)
Date received	May 12, 2008
Decision date	Mar 6, 2009
Days to decision	298 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**O-Two Medical Technologies, Inc.**
Location	Mississauga, CA
Contact	PAUL DRYDEN
510(k) history	8 submissions · 8 cleared · 2005-2018