FDA 510(k) Premarket Notification

K183512 Moore Park Mask

CLEARED

May 7, 2019
140 days to decision

K183512 · Product code: **BZD** · Anesthesiology
Source: https://www.510kdatabase.net/k183512/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Dec 18, 2018
Decision date	May 7, 2019
Days to decision	140 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Resmed, Ltd.**
Location	Poway, CA, US
Contact	Nerida Hunt
Website	http://www.resmed.com/
510(k) history	103 submissions · 103 cleared · 1996-2019

REGULATORY CONSULTANT

Consulting firm	**Resmed Corp**
Contact	Sheila Bruschi

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/k183512/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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