FDA 510(k) Premarket Notification

K122715 STELLAR 150

CLEARED

Jun 17, 2013
285 days to decision

K122715 · Product code: **MNT** · Anesthesiology
Source: https://www.510kdatabase.net/k122715/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Minimal Ventilatory Support, Facility Use (MNT)
Date received	Sep 5, 2012
Decision date	Jun 17, 2013
Days to decision	285 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Resmed Germany, Inc.**
Location	Poway, CA, US
Contact	JIM CASSI
510(k) history	8 submissions · 8 cleared · 2006-2015

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k122715/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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