K161492 Juno VPAP ST-A

CLEARED

Jan 19, 2017
232 days to decision

K161492 · Product code: **MNS** · Anesthesiology
Source: https://www.510kdatabase.net/k161492/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Non-life-supporting (MNS)
Date received	Jun 1, 2016
Decision date	Jan 19, 2017
Days to decision	232 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Resmed Corp**
Contact	Larissa D'Andrea

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

CLINICAL EVIDENCE - NCT02317042

Juno Perth Clinical Trial

Status	Terminated
Enrollment	25 patients (actual)
Study sites	2 sites
Condition studied	Respiratory Insufficiency; Obesity Hypoventilation Syndrome; Chronic Obstructive Pulmonary Disease (COPD); Neuromuscular Disease; Upper Airway Obstruction
Primary purpose	Treatment
Study type	Interventional
Study design	Crossover
Masking	Triple
Completion date	Nov 29, 2015
Sponsor	ResMed (Industry)

Primary outcome

Apnoea-Hypopnoea Index (AHI)

Secondary outcome

Oxygen Desaturation Index

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT02317042