FDA 510(k) Premarket Notification

K160836 Menai System

CLEARED

Dec 15, 2016
265 days to decision

K160836 · Product code: **BZD** · Anesthesiology
Source: https://www.510kdatabase.net/k160836/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Mar 25, 2016
Decision date	Dec 15, 2016
Days to decision	265 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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