FDA 510(k) Premarket Notification

CLEARED

K180388 Transcend 365 miniCPAP System

Nov 30, 2018
290 days to decision

K180388 · Product code: **BZD** · Anesthesiology
Source: https://www.510kdatabase.net/k180388/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Feb 13, 2018
Decision date	Nov 30, 2018
Days to decision	290 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Somnetics International, Inc.**
Location	New Brighton, MN, US
Contact	Eric Becker
510(k) history	3 submissions · 3 cleared · 2013-2018

REGULATORY CONSULTANT

Consulting firm	**Bluebird Consulting, LLC**
Contact	Melinda Swanson

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