

K151683 SleepWeaver Advance Pediatric Nasal CPAP MaskApr 5, 2016
288 days to decisionK151683 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k151683/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Jun 22, 2015
Decision date	Apr 5, 2016
Days to decision	288 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Circadiance, LLC
Location	Murrysville, PA, US
Contact	David Groll
510(k) history	5 submissions · 5 cleared · 2009-2017

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