

K153387 Luna CPAP and Auto CPAP SystemSep 8, 2016
290 days to decisionK153387 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k153387/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Nov 23, 2015
Decision date	Sep 8, 2016
Days to decision	290 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	3B Medical, Inc.
Location	Lake Wales, FL, US
Contact	ALEX LUCIO
510(k) history	10 submissions · 10 cleared · 2013-2022

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