

K201620 Luna® G3 BPAP 25AJan 29, 2021
228 days to decisionK201620 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k201620/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Jun 15, 2020
Decision date	Jan 29, 2021
Days to decision	228 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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