

K212263 Luna G3 BPAP SystemMar 25, 2022
248 days to decisionK212263 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k212263/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Jul 20, 2021
Decision date	Mar 25, 2022
Days to decision	248 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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