

K131901 INVOLVE NASAL MASK, INVOLVE FULL FACE MASK, INVOLVE N2

Dec 23, 2013
181 days to decision

K131901 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k131901/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Jun 25, 2013
Decision date	Dec 23, 2013
Days to decision	181 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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k131901/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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