

K233555 AF531 Oro-Nasal EE Leak 1 Face MaskJul 31, 2024
268 days to decisionK233555 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k233555/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Nov 6, 2023
Decision date	Jul 31, 2024
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	AF531 Oro-Nasal EE Leak 2 Face Mask

APPLICANT

Company	Philips Respironics
Location	Murrysville, PA, US
Contact	Emily Tobin
510(k) history	1 submissions · 1 cleared · 2024-2024

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