

K243023 WiZARD 520 Full Face MaskMay 23, 2025
238 days to decisionK243023 · Product code: **BZD** · AnesthesiologySource: <https://www.510kdatabase.net/k243023/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Sep 27, 2024
Decision date	May 23, 2025
Days to decision	238 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Wellell, Inc.
Location	New Taipei City, TW
Contact	Chieh Yang
510(k) history	2 submissions · 2 cleared · 2025-2025

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