

K231728 BiWaze Clear SystemApr 8, 2024
300 days to decisionK231728 · Product code: **NHJ** · Anesthesiology
Source: <https://www.510kdatabase.net/k231728/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Positive Pressure Breathing, Intermittent (NHJ)
Date received	Jun 13, 2023
Decision date	Apr 8, 2024
Days to decision	300 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Abmrc, LLC
Location	Charleston, SC, US
Contact	Leah Noaeill
510(k) history	3 submissions · 3 cleared · 2020-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231728/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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