

K213564 BiWaze Clear SystemDec 21, 2022
407 days to decisionK213564 · Product code: **NHJ** · Anesthesiology
Source: <https://www.510kdatabase.net/k213564/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Positive Pressure Breathing, Intermittent (NHJ)
Date received	Nov 9, 2021
Decision date	Dec 21, 2022
Days to decision	407 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/k213564/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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