

K242717 Laboratorios Biogalenic Sterile Water for Inhalation, USPJan 30, 2025
142 days to decisionK242717 · Product code: **BTT** · Anesthesiology
Source: <https://www.510kdatabase.net/k242717/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Humidifier, Respiratory Gas, (direct Patient Interface) (BTT)
Date received	Sep 10, 2024
Decision date	Jan 30, 2025
Days to decision	142 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Laboratorios Biogalenic S.A. DE C.V.
Location	San Salvador, SV
Contact	Roberto Quiñonez
510(k) history	3 submissions · 3 cleared · 2025-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242717/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026