

K251419 Laboratorios Biogalenic Sterile Water for Inhalation, USPJan 14, 2026
252 days to decisionK251419 · Product code: **BTT** · Anesthesiology
Source: <https://www.510kdatabase.net/k251419/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Humidifier, Respiratory Gas, (direct Patient Interface) (BTT)
Date received	May 7, 2025
Decision date	Jan 14, 2026
Days to decision	252 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

REGULATORY CONSULTANT

Consulting firm	Herschel J. Gaddy & Associates
Contact	Jennifer Prussman

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251419/> 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