

K254078 HVT 2.0Apr 13, 2026
116 days to decisionK254078 · Product code: **BTT** · Anesthesiology
Source: <https://www.510kdatabase.net/k254078/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Humidifier, Respiratory Gas, (direct Patient Interface) (BTT)
Date received	Dec 18, 2025
Decision date	Apr 13, 2026
Days to decision	116 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Vapotherm, Inc.
Location	Annapolis, MD, US
Contact	Michael Webb
510(k) history	13 submissions · 12 cleared · 2000-2026

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