

K203357 HVT 2.0Aug 25, 2021
282 days to decisionK203357 · Product code: **BTT** · Anesthesiology
Source: <https://www.510kdatabase.net/k203357/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Humidifier, Respiratory Gas, (direct Patient Interface) (BTT)
Date received	Nov 16, 2020
Decision date	Aug 25, 2021
Days to decision	282 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Vapotherm, Inc.
Location	Annapolis, MD, US
Contact	Dennis Francoeur
Website	https://vapotherm.com/
510(k) history	13 submissions · 12 cleared · 2000-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203357/> 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 25, 2026