

K191010 Palladium High Flow Therapy SystemOct 10, 2019
177 days to decisionK191010 · Product code: **BTT** · AnesthesiologySource: <https://www.510kdatabase.net/k191010/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Humidifier, Respiratory Gas, (direct Patient Interface) (BTT)
Date received	Apr 16, 2019
Decision date	Oct 10, 2019
Days to decision	177 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

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

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