

**K252849 AffloVest® Mobile Airway Clearance Therapy**Apr 30, 2026  
234 days to decisionK252849 · Product code: **BYI** · Anesthesiology  
Source: <https://www.510kdatabase.net/k252849/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Percussor, Powered-electric (BYI)
Date received	Sep 8, 2025
Decision date	Apr 30, 2026
Days to decision	234 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Tactile Medical</b>
Location	Minneapolis, MN, US
Contact	Sunday Hoy
Website	<a href="https://tactilemedical.com">https://tactilemedical.com</a>
510(k) history	2 submissions · 2 cleared · 2024-2026

Tactile Medical develops at-home therapy devices for chronic swelling conditions. The company specializes in pneumatic compression systems treating lymphedema and chronic venous insufficiency. Headquartered in Minneapolis, Minnesota, Tactile Medical combines innovative devices with personalized patient support and reimbursement expertise. The company has received FDA 510(k) clearances from total submissions. Tactile Medical's cleared devices span anesthesiology and cardiovascular categories, with first clearance in 2024 and most recent clearance in 2026. The company remai...

**REGULATORY CONSULTANT**

---

Consulting firm	<b>DuVal &amp; Associates, P.A.</b>
Contact	Jessica Buell

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

---