

K254040 LungFlow Basket CatheterMar 12, 2026
86 days to decisionK254040 · Product code: **KTI** · Anesthesiology
Source: <https://www.510kdatabase.net/k254040/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bronchoscope Accessory (KTI)
Date received	Dec 16, 2025
Decision date	Mar 12, 2026
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Free Flow Medical, Inc.
Location	Fremont, CA, US
Contact	Mark Mathis
Website	https://www.freeflowmedical.com
510(k) history	1 submissions · 1 cleared · 2026-2026

Free Flow Medical, Inc. is a lung specialist company developing targeted treatments for chronic obstructive pulmonary disease and severe emphysema. The company operates with a manufacturing facility in Fremont, US. Free Flow Medical has received FDA 510(k) clearance from total submission. The company specializes in Anesthesiology devices. The latest clearance was granted in 2026, reflecting active regulatory engagement. The company's primary product focus includes bronchoscopic lung volume reduction systems designed for severe emphysema patients. These devices aim to impr...