

**K221058 LungTrainer (MD2 & MD3)**Jul 5, 2023  
450 days to decisionK221058 · Product code: **BWF** · Anesthesiology  
Source: <https://www.510kdatabase.net/k221058/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Therapeutic (incentive) (BWF)
Date received	Apr 11, 2022
Decision date	Jul 5, 2023
Days to decision	450 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Lung Trainers, LLC</b>
Location	Miami, FL, US
Contact	Frank Acosta
510(k) history	1 submissions · 1 cleared · 2023-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Medical Device Academy, Inc.</b>
Contact	Robert Packard

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

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