FDA 510(k) Premarket Notification

K221058 LungTrainer (MD2 & MD3)

CLEARED

Jul 5, 2023
450 days to decision

K221058 · Product code: **BWF** · Anesthesiology
Source: https://www.510kdatabase.net/k221058/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Medical Device Academy, Inc.**
Contact	Robert Packard

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