

K222018 Breathe+Jun 2, 2023
329 days to decisionK222018 · Product code: **BWF** · AnesthesiologySource: <https://www.510kdatabase.net/k222018/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Therapeutic (incentive) (BWF)
Date received	Jul 8, 2022
Decision date	Jun 2, 2023
Days to decision	329 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Peep Medical, LLC Db a Go2 Devices
Location	Houston, TX, US
Contact	Paul Dryden
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Peep Medical, LLC
Contact	Paul Dryden

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k222018/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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