

K203378 PulsehalerMar 31, 2021
134 days to decisionK203378 · Product code: **BWF** · Anesthesiology
Source: <https://www.510kdatabase.net/k203378/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Therapeutic (incentive) (BWF)
Date received	Nov 17, 2020
Decision date	Mar 31, 2021
Days to decision	134 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Respinova, Ltd.
Location	Herzliya, IL
Contact	Cliff Ansel
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Ironstone Product Development, Inc.
Contact	Joel Ironstone

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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