FDA 510(k) Premarket Notification

K203378 Pulsehaler

CLEARED

Mar 31, 2021
134 days to decision

K203378 · 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