FDA 510(k) Premarket Notification

K212938 Vitalograph Model 6000 Alpha

CLEARED

Jan 26, 2022
133 days to decision

K212938 · Product code: **BZG** · Anesthesiology
Source: https://www.510kdatabase.net/k212938/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Diagnostic (BZG)
Date received	Sep 15, 2021
Decision date	Jan 26, 2022
Days to decision	133 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Vitalograph (Ireland) , Ltd.**
Location	Ennis, Co. Clare, IE
Contact	Tony O'Hanlon
510(k) history	12 submissions · 12 cleared · 2008-2023

REGULATORY CONSULTANT

Consulting firm	**ProMedic Consulting, LLC**
Contact	Paul Dryden

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