

K201562 SpirotracOct 14, 2020
126 days to decisionK201562 · Product code: **BZG** · Anesthesiology
Source: <https://www.510kdatabase.net/k201562/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Diagnostic (BZG)
Date received	Jun 10, 2020
Decision date	Oct 14, 2020
Days to decision	126 days
Third-party review	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

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