

K161676 Q13 SPIROLYSER®Oct 20, 2016
125 days to decisionK161676 · Product code: **BZG** · Anesthesiology
Source: <https://www.510kdatabase.net/k161676/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Diagnostic (BZG)
Date received	Jun 17, 2016
Decision date	Oct 20, 2016
Days to decision	125 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fim Medical
Location	Lyon, FR
Contact	LIZA PERRAT
510(k) history	4 submissions · 4 cleared · 2002-2016

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