

K160116 SpiroScoutOct 7, 2016
262 days to decisionK160116 · Product code: **BZG** · Anesthesiology
Source: <https://www.510kdatabase.net/k160116/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Diagnostic (BZG)
Date received	Jan 19, 2016
Decision date	Oct 7, 2016
Days to decision	262 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ganshorn Medizin Electronic GmbH
Location	Niederlauer, DE
Contact	Stefan Ponto
510(k) history	2 submissions · 2 cleared · 2016-2024

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