

**K160253 Vitalograph Model 6300 micro**Aug 26, 2016  
207 days to decisionK160253 · Product code: **BZG** · Anesthesiology  
Source: <https://www.510kdatabase.net/k160253/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Diagnostic (BZG)
Date received	Feb 1, 2016
Decision date	Aug 26, 2016
Days to decision	207 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Vitalograph (Ireland) , Ltd.</b>
Location	Ennis, Co. Clare, IE
Contact	TOM J HEALY
510(k) history	12 submissions · 12 cleared · 2008-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k160253/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026