

**K202837 GoSpiro**Dec 4, 2020  
70 days to decisionK202837 · Product code: **BZG** · Anesthesiology  
Source: <https://www.510kdatabase.net/k202837/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Spirometer, Diagnostic (BZG)
Date received	Sep 25, 2020
Decision date	Dec 4, 2020
Days to decision	70 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Monitored Therapeutics, Inc.</b>
Location	Dublin, OH, US
Contact	Michael Taylor
510(k) history	2 submissions · 2 cleared · 2017-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>Monitored Therapeutics, Inc. C/O Promedic, LLC</b>
Contact	Paul Dryden

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k202837/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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