

**K213754 SpiroHome Personal, SpiroHome Clinic**Jun 12, 2023  
559 days to decisionK213754 · Product code: **BZG** · Anesthesiology  
Source: <https://www.510kdatabase.net/k213754/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Diagnostic (BZG)
Date received	Nov 30, 2021
Decision date	Jun 12, 2023
Days to decision	559 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Inofab Saglik Teknolojileri A.S</b>
Location	Cankaya, Ankara, TR
Contact	Deniz Sarp
510(k) history	1 submissions · 1 cleared · 2023-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Arazy Group Consultants, Inc.</b>
Contact	Ray Kelly

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/k213754/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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