

**K210112 XChange Device, XChange System**Jan 30, 2023  
741 days to decisionK210112 · Product code: **CCK** · Anesthesiology  
Source: <https://www.510kdatabase.net/k210112/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Gas, Carbon-dioxide, Gaseous-phase (CCK)
Date received	Jan 19, 2021
Decision date	Jan 30, 2023
Days to decision	741 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Pneuma Therapeutics, Inc.</b>
Location	Tucson, AZ, US
Contact	William Densel
510(k) history	1 submissions · 1 cleared · 2023-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Regulatory and Quality Solutions, LLC</b>
Contact	Michele McDonald

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/k210112/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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