FDA 510(k) Premarket Notification

CLEARED

K210112 XChange Device, XChange System

Jan 30, 2023
741 days to decision

K210112 · Product code: **CCK** · Anesthesiology
Source: https://www.510kdatabase.net/k210112/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Regulatory and Quality Solutions, LLC**
Contact	Michele McDonald

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