

K230501 Spirobank OxiDec 15, 2023
294 days to decisionK230501 · Product code: **BZG** · Anesthesiology
Source: <https://www.510kdatabase.net/k230501/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Diagnostic (BZG)
Date received	Feb 24, 2023
Decision date	Dec 15, 2023
Days to decision	294 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Mir Medical International Research USA
Location	New Berlin, WI, US
Contact	Dale Novy
510(k) history	1 submissions · 1 cleared · 2023-2023

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