FDA 510(k) Premarket Notification

K222525 Alveoair Digital Spirometer

CLEARED

Aug 28, 2023
371 days to decision

K222525 · Product code: **BZG** · Anesthesiology
Source: https://www.510kdatabase.net/k222525/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Diagnostic (BZG)
Date received	Aug 22, 2022
Decision date	Aug 28, 2023
Days to decision	371 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Roundworks Technologies Private Limited**
Location	Wakad, Pune, IN
Contact	Prashant Patel
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**IZiel Healthcare**
Contact	Ankur Naik

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k222525/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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