FDA 510(k) Premarket Notification

K222443 Air Smart Extra Spirometer

CLEARED

Aug 9, 2023
362 days to decision

K222443 · Product code: **BZG** · Anesthesiology
Source: https://www.510kdatabase.net/k222443/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Diagnostic (BZG)
Date received	Aug 12, 2022
Decision date	Aug 9, 2023
Days to decision	362 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Feellife Health, Inc.**
Location	Shenzhen, CN
Contact	May Xiao
510(k) history	2 submissions · 2 cleared · 2020-2023

REGULATORY CONSULTANT

Consulting firm	**Guangzhou Osmunda Medical Device Technical Service Co., Ltd.**
Contact	Olivia Meng

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/k222443/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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