FDA 510(k) Premarket Notification

K232588 Aluna 2

CLEARED

Nov 25, 2024
458 days to decision

K232588 · Product code: **BZH** · Anesthesiology
Source: https://www.510kdatabase.net/k232588/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Meter, Peak Flow, Spirometry (BZH)
Date received	Aug 25, 2023
Decision date	Nov 25, 2024
Days to decision	458 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Knox Medical Diagnostics**
Location	San Francisco, CA, US
Contact	Michael Raftery
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	**RQM+**
Contact	Allison Komiyama

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