FDA 510(k) Premarket Notification

K193311 Aluna

CLEARED

Mar 25, 2020
117 days to decision

K193311 · Product code: **BZH** · Anesthesiology
Source: https://www.510kdatabase.net/k193311/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Meter, Peak Flow, Spirometry (BZH)
Date received	Nov 29, 2019
Decision date	Mar 25, 2020
Days to decision	117 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Knox Medical Diagnostics, Inc.**
Location	San Francisco, CA, US
Contact	Charvi Shetty
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**Acknowledge Regulatory Strategies**
Contact	Pierre Bounaud

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