FDA 510(k) Premarket Notification

K233056 EpiZact

CLEARED

Nov 2, 2023
38 days to decision

K233056 · Product code: **FMF** · Anesthesiology
Source: https://www.510kdatabase.net/k233056/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Sep 25, 2023
Decision date	Nov 2, 2023
Days to decision	38 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Guidestar Medical Devices**
Location	Victoria, CA
Contact	Michael Dolphin
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Regulatory Technology Services, LLC**
Contact	Prithul Bom

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