

K233056 EpiZactNov 2, 2023
38 days to decisionK233056 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233056/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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