

K203264 MicroDose InjectorApr 26, 2021
172 days to decisionK203264 · Product code: **FMF** · Ophthalmic
Source: <https://www.510kdatabase.net/k203264/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Nov 5, 2020
Decision date	Apr 26, 2021
Days to decision	172 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medone Surgical, Inc.
Location	Sarasota, FL, US
Contact	Bruce Beckstein
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Elkin Rc, LLC
Contact	Darla Elkin

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203264/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026