

K253769 Instylla Delivery KitDec 22, 2025
27 days to decisionK253769 · Product code: **FMF** · General HospitalSource: <https://www.510kdatabase.net/k253769/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Syringe, Piston (FMF)
Date received	Nov 25, 2025
Decision date	Dec 22, 2025
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Instylla, Inc.
Location	Waltham, MA, US
Contact	Jennifer Greer
510(k) history	9 submissions · 9 cleared · 2019-2025

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