FDA 510(k) Premarket Notification

K213632 Instylla Delivery Kit

CLEARED

Feb 10, 2022
85 days to decision

K213632 · Product code: **FMF** · General Hospital
Source: https://www.510kdatabase.net/k213632/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Syringe, Piston (FMF)
Date received	Nov 17, 2021
Decision date	Feb 10, 2022
Days to decision	85 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