

K243149 Microliter Dosing Syringe (9, 20, 25, 37.5, 50 and 100 microliter models)

Dec 20, 2024
81 days to decision

K243149 · Product code: **QLY** · General Hospital
Source: <https://www.510kdatabase.net/k243149/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ophthalmic Syringe (QLY)
Date received	Sep 30, 2024
Decision date	Dec 20, 2024
Days to decision	81 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Congruence Medical Solutions, LLC
Location	Baltimore, MD, US
Contact	Gautam Shetty
510(k) history	1 submissions · 1 cleared · 2024-2024

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k243149/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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