FDA 510(k) Premarket Notification

K241821 Luer Lock Syringe with Safety Needle

CLEARED

Sep 20, 2024
88 days to decision

K241821 · Product code: **FMF** · General Hospital
Source: https://www.510kdatabase.net/k241821/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Jun 24, 2024
Decision date	Sep 20, 2024
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Luer Lock Syringe with Exchangeable Needle; Luer Lock Syringe with Blunt Fill Needle

APPLICANT

Company	**Sol-Millennium Medical, Inc.**
Location	Lawrenceville, GA, US
Contact	Manu Kalia
510(k) history	12 submissions · 12 cleared · 2014-2025

REGULATORY CONSULTANT

Consulting firm	**Shanghai Mind-Link Consulting Co., Ltd.**
Contact	Alice Huang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov