FDA 510(k) Premarket Notification

CLEARED

K222925 Hypodermic Syringes & Needle

Jul 18, 2023
295 days to decision

K222925 · Product code: **FMF** · General Hospital
Source: https://www.510kdatabase.net/k222925/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Sep 26, 2022
Decision date	Jul 18, 2023
Days to decision	295 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Lifelong Meditech Private Limited**
Location	Gurgaon, IN
Contact	Mr. Hamendra Nath Srivastava
510(k) history	2 submissions · 2 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	**Alceon**
Contact	Atonu Dutta

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