FDA 510(k) Premarket Notification

K240961 Disposable Pen Injector Assembly

CLEARED

Aug 15, 2024
129 days to decision

K240961 · Product code: **FMF** · General Hospital
Source: https://www.510kdatabase.net/k240961/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Apr 8, 2024
Decision date	Aug 15, 2024
Days to decision	129 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Wuxi Nest Biotechnology Co., Ltd.**
Location	Wuxi, CN
Contact	Cheng Zhiwei
510(k) history	4 submissions · 4 cleared · 2021-2024

REGULATORY CONSULTANT

Consulting firm	**Icas Group**
Contact	Ryan Li

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