FDA 510(k) Premarket Notification

K234024 HWJECT Auto-disable syringe

CLEARED

Mar 19, 2024
90 days to decision

K234024 · Product code: **FMF** · General Hospital
Source: https://www.510kdatabase.net/k234024/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Dec 20, 2023
Decision date	Mar 19, 2024
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Anhui Hongyu Wuzhou Medical Manufacturer Co., Ltd.**
Location	Taihu, Anqing City, CN
Contact	Bingyi Xiang
510(k) history	12 submissions · 12 cleared · 2019-2024

REGULATORY CONSULTANT

Consulting firm	**Shanghai Mind-Link Consulting Co., Ltd.**
Contact	Tanya Wang

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