FDA 510(k) Premarket Notification

K230061 Insulin Syringe

CLEARED

Nov 30, 2023
325 days to decision

K230061 · Product code: **FMF** · General Hospital
Source: https://www.510kdatabase.net/k230061/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Jan 9, 2023
Decision date	Nov 30, 2023
Days to decision	325 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	Evan Hu

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