FDA 510(k) Premarket Notification

CLEARED

K211242 Promisemed Sterile Hypodermic Syringes, Verifine Sterile Hypodermic Syringes

Sep 9, 2021
136 days to decision

K211242 · Product code: **FMF** · General Hospital
Source: https://www.510kdatabase.net/k211242/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Apr 26, 2021
Decision date	Sep 9, 2021
Days to decision	136 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Promisemed Hangzhou Meditech Co., Ltd.**
Location	Hangzhou, CN
Contact	Zearou Yang
510(k) history	34 submissions · 34 cleared · 2017-2026

REGULATORY CONSULTANT

Consulting firm	**Vee Care (Asia) Limited**
Contact	Wei Shan Hsu

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