FDA 510(k) Premarket Notification

CLEARED

K210065 Verifine Safety Type Insulin Pen Needle

Apr 22, 2021
101 days to decision

K210065 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k210065/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jan 11, 2021
Decision date	Apr 22, 2021
Days to decision	101 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