FDA 510(k) Premarket Notification

CLEARED

K221368 Promisemed Blood Lancet, VeriFine Safety Lancet, VeriFine Mini-Safety Lancet

Jun 9, 2022
28 days to decision

K221368 · Product code: **FMK** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k221368/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Single Use Only Blood Lancet With An Integral Sharps Injury Prevention Feature (FMK)
Date received	May 12, 2022
Decision date	Jun 9, 2022
Days to decision	28 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