FDA 510(k) Premarket Notification

CLEARED

K223643 Verifine® Ease Lancing Device, Verifine® Lancing Device

Feb 21, 2023
77 days to decision

K223643 · Product code: **QRL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k223643/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multiple Use Blood Lancet For Single Patient Use Only (QRL)
Date received	Dec 6, 2022
Decision date	Feb 21, 2023
Days to decision	77 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