FDA 510(k) Premarket Notification

K242622 Sterile Lancets for Single Use

CLEARED

Oct 28, 2024
55 days to decision

K242622 · Product code: **QRK** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k242622/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single Use Only Blood Lancet Without An Integral Sharps Injury Prevention Feature (QRK)
Date received	Sep 3, 2024
Decision date	Oct 28, 2024
Days to decision	55 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ningbo Caremed Medical Products Co., Ltd.**
Location	Ningbo, CN
Contact	Cen Wei
510(k) history	2 submissions · 2 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	**Landlink Healthcare Technology (Shanghai) Co., Ltd.**
Contact	Kyra Kang

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