FDA 510(k) Premarket Notification

CLEARED

K222472 Lancing System, Sterile Lancet for Single Use, Lancing Device

Nov 30, 2022
106 days to decision

K222472 · Product code: **QRL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k222472/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multiple Use Blood Lancet For Single Patient Use Only (QRL)
Date received	Aug 16, 2022
Decision date	Nov 30, 2022
Days to decision	106 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shandong Lianfa Medical Plastic Products Co. , Ltd.**
Location	Jinan, CN
Contact	Charles Shen
510(k) history	2 submissions · 2 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Manton Business and Technology Services**
Contact	Charles Shen

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