FDA 510(k) Premarket Notification

K221970 Lancing device

CLEARED

Aug 30, 2022
56 days to decision

K221970 · Product code: **QRL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k221970/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multiple Use Blood Lancet For Single Patient Use Only (QRL)
Date received	Jul 5, 2022
Decision date	Aug 30, 2022
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**SteriLance Medical (Suzhou), Inc.**
Location	Suzhou, CN
Contact	Susan Sun
510(k) history	8 submissions · 8 cleared · 2016-2025