FDA 510(k) Premarket Notification

K221419 TD-5010 Lancing Device and TD-5084 Sterile Lancets

CLEARED

Jan 20, 2023
249 days to decision

K221419 · Product code: **QRL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k221419/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multiple Use Blood Lancet For Single Patient Use Only (QRL)
Date received	May 16, 2022
Decision date	Jan 20, 2023
Days to decision	249 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Gostar Co., Ltd.**
Location	New Taipei City, TW
Contact	Pei-Fen Yang
510(k) history	3 submissions · 3 cleared · 2023-2024