FDA 510(k) Premarket Notification

K253706 Lancing device (HH-XV-T)

CLEARED

Dec 9, 2025
15 days to decision

K253706 · Product code: **QRL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k253706/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Multiple Use Blood Lancet For Single Patient Use Only (QRL)
Date received	Nov 24, 2025
Decision date	Dec 9, 2025
Days to decision	15 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Tianjin Huahong Technology Co., Ltd.**
Location	Tianjin, CN
Contact	Ningning Wang
510(k) history	11 submissions · 11 cleared · 2021-2026