FDA 510(k) Premarket Notification

K220475 Lancet (I, II, III, V, VI)

CLEARED

Jul 6, 2022
138 days to decision

K220475 · Product code: **QRL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k220475/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multiple Use Blood Lancet For Single Patient Use Only (QRL)
Date received	Feb 18, 2022
Decision date	Jul 6, 2022
Days to decision	138 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Lancing device (HH-X-T, HH-XIII-T, HH-XV-T, HH-XVI-T, HH-XVII-T, HH-XVIII-T, HH-XIX, HH-XXI-T, HH-XXII-T, HH-XXIII-T, HH-XXIV-T)

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Landlink Healthcare Technology (Shanghai) Co., Ltd.**
Contact	Stuart Situ

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