

K220372 Heel Stick Safety Lancet (HHZ-II, HHZ-III)May 17, 2022
97 days to decisionK220372 · Product code: **FMK** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k220372/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single Use Only Blood Lancet With An Integral Sharps Injury Prevention Feature (FMK)
Date received	Feb 9, 2022
Decision date	May 17, 2022
Days to decision	97 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	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](https://accessdata.fda.gov)

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