

K221383 MedtFine Blood LancetSep 21, 2022
131 days to decisionK221383 · Product code: **QRK** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k221383/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single Use Only Blood Lancet Without An Integral Sharps Injury Prevention Feature (QRK)
Date received	May 13, 2022
Decision date	Sep 21, 2022
Days to decision	131 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shanghai Carelife International Trading Co. , Ltd.
Location	Shanghai, Pudong, CN
Contact	Zhang Xiaoying
510(k) history	2 submissions · 2 cleared · 2014-2022

REGULATORY CONSULTANT

Consulting firm	Shanghai Mind-Link Consulting Co., Ltd.
Contact	Evan Hu

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

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