

K221778 Disposable Safety LancetsOct 3, 2022
104 days to decisionK221778 · Product code: **FMK** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k221778/>**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	Jun 21, 2022
Decision date	Oct 3, 2022
Days to decision	104 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Suzhou Kyuan Medical Apparatus Co., Ltd.
Location	Suzhou, CN
Contact	Shi Ye
510(k) history	2 submissions · 2 cleared · 2022-2022

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