

K221604 SafetiHeel, MediHeel, NovaplusAug 22, 2022
81 days to decisionK221604 · Product code: **FMK** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k221604/>**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 2, 2022
Decision date	Aug 22, 2022
Days to decision	81 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nsp Tech Pte, Ltd.
Location	Singapore, SG
Contact	HC Tan
510(k) history	5 submissions · 5 cleared · 2019-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221604/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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