

K223201 TAP LancetApr 19, 2023
187 days to decisionK223201 · Product code: **FMK** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k223201/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Single Use Only Blood Lancet With An Integral Sharps Injury Prevention Feature (FMK)
Date received	Oct 14, 2022
Decision date	Apr 19, 2023
Days to decision	187 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Yourbio Health, Inc.
Location	Medford, MA, US
Contact	Sean McCarthy
510(k) history	1 submissions · 0 cleared · 2023-2023

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