

K213683 Promisemed Fine Biopsy NeedleApr 22, 2022
151 days to decisionK213683 · Product code: **KNW** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k213683/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Nov 22, 2021
Decision date	Apr 22, 2022
Days to decision	151 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Promisemed Hangzhou Meditech Co., Ltd.
Location	Hangzhou, CN
Contact	Zearou Yang
510(k) history	34 submissions · 34 cleared · 2017-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213683/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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