

K212819 Disposable Biopsy Refill NeedleJul 6, 2022
306 days to decisionK212819 · Product code: **FCG** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k212819/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biopsy Needle (FCG)
Date received	Sep 3, 2021
Decision date	Jul 6, 2022
Days to decision	306 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Suzhou Leapmed Healthcare Corporation
Location	Suzhou, CN
Contact	Yu Zhu
510(k) history	4 submissions · 4 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	Shanghai Truthful Information Technology Co., Ltd.
Contact	Boyle Wang

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

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