

K212284 Disposable Automatic Core Biopsy InstrumentNov 10, 2021
112 days to decisionK212284 · Product code: **KNW** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k212284/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Jul 21, 2021
Decision date	Nov 10, 2021
Days to decision	112 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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