

K231721 Disposable Hot Biopsy ForcepsDec 14, 2023
184 days to decisionK231721 · Product code: **KGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k231721/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Forceps, Biopsy, Electric (KGE)
Date received	Jun 13, 2023
Decision date	Dec 14, 2023
Days to decision	184 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Beijing Zksk Technology Co., Ltd.
Location	Beijing, CN
Contact	Ma Li
510(k) history	6 submissions · 6 cleared · 2022-2025

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231721/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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