

K242192 Disposable SphincterotomeFeb 6, 2025
195 days to decisionK242192 · Product code: **KNS** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k242192/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Electrosurgical, Endoscopic (with Or Without Accessories) (KNS)
Date received	Jul 26, 2024
Decision date	Feb 6, 2025
Days to decision	195 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	Li Ma
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/k242192/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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