

K232476 Disposable SphincterotomeNov 7, 2023
83 days to decisionK232476 · Product code: **KNS** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k232476/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Electrosurgical, Endoscopic (with Or Without Accessories) (KNS)
Date received	Aug 16, 2023
Decision date	Nov 7, 2023
Days to decision	83 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Zhejiang Soudon Medical Technology Co., Ltd.
Location	Hangzhou, CN
Contact	Wang Junshi
510(k) history	4 submissions · 4 cleared · 2023-2026

REGULATORY CONSULTANT

Consulting firm	Shanghai Vanhe Consulting Co., Ltd.
Contact	Wang Nick

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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