

K232825 Disposable SphincterotomeMar 29, 2024
198 days to decisionK232825 · Product code: **KNS** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k232825/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Electrosurgical, Endoscopic (with Or Without Accessories) (KNS)
Date received	Sep 13, 2023
Decision date	Mar 29, 2024
Days to decision	198 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jiangsu Vedkang Medical Science and Technology Co., Ltd.
Location	Changzhou, CN
Contact	Yulu Shi
510(k) history	7 submissions · 7 cleared · 2022-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232825/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026