

K251104 SureTome™ SW Sphincterotome with DomeTipSep 29, 2025
171 days to decisionK251104 · Product code: **KNS** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k251104/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Electrosurgical, Endoscopic (with Or Without Accessories) (KNS)
Date received	Apr 11, 2025
Decision date	Sep 29, 2025
Days to decision	171 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Wilson Cook Medical
Location	Winstrom-Salem, NC, US
Contact	Kaylin Davis
510(k) history	2 submissions · 2 cleared · 2022-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251104/> 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 14, 2026