

K172288 Fusion OMNI SphincterotomeApr 17, 2018
260 days to decisionK172288 · Product code: **KNS** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k172288/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Electrosurgical, Endoscopic (with Or Without Accessories) (KNS)
Date received	Jul 31, 2017
Decision date	Apr 17, 2018
Days to decision	260 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Wilson-Cook Medical Inc./Cook Endoscopy
Location	Winstrom-Salem, NC, US
Contact	Sierra Lowe
510(k) history	7 submissions · 7 cleared · 2012-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k172288/> 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 June 28, 2026