

**K172665 Classic Cotton Cannulatome® , CannulaTome II®
Double Lumen Sphincterotome, Cotton CannulaTome II® PC,
UTS® Ultra Taper Sphincterotome, Tri-Tome pc® Triple Lumen
Sphincterotome, Howell D.A.S.H.® Sphincterotome with
DomeTip®, Billroth II Sphincterotome, Soehendra® BII
Sphincterotome, Models ACU-1 and ACU-1-VL active cords**

May 24, 2018
261 days to decision

K172665 · Product code: **KNS** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k172665/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Electrosurgical, Endoscopic (with Or Without Accessories) (KNS)
Date received	Sep 5, 2017
Decision date	May 24, 2018
Days to decision	261 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	Theresa de Prat
510(k) history	7 submissions · 7 cleared · 2012-2019

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k172665/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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