

K052051 OMNI SPHINCTEROTOME

Aug 5, 2005
7 days to decision

K052051 · Product code: **KNS** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k052051/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Unit, Electrosurgical, Endoscopic (with Or Without Accessories) (KNS)
Date received	Jul 29, 2005
Decision date	Aug 5, 2005
Days to decision	7 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Wilson-Cook Medical, Inc.
Location	Winstrom-Salem, NC, US
Contact	MARGE WALLS-WALKER
510(k) history	125 submissions · 118 cleared · 1985-2026