

K171989 Classic ERCP Catheter and Huibregtse-Katon ERCP Catheter and Huibregtse-Katon Angled, Glo-Tip ERCP Catheter, Glo-Tip II Double Lumen ERCP Catheter & w/ Radiopaque Bands, Fusion ERCP Catheter with DomeTip and Fusion OMNI ERCP Catheter with DomeTip, Haber RAMP Catheter, Soehendra Universal CatheterMar 20, 2018
260 days to decisionK171989 · Product code: **ODD** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k171989/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Retrograde Cholangiopancreatography (ercp) Cannula (ODD)
Date received	Jul 3, 2017
Decision date	Mar 20, 2018
Days to decision	260 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Wilson-Cook Medical, Inc.
Location	Winstrom-Salem, NC, US
Contact	Ashley Howard
510(k) history	124 submissions · 117 cleared · 1985-2025

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