

K261658 LoFric Origo Pro Coudé

Jul 17, 2026
59 days to decision

K261658 · Product code: **EZD** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k261658/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Straight (EZD)
Date received	May 19, 2026
Decision date	Jul 17, 2026
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Wellspect AB
Location	M?lndal, SE
Contact	Emad Ramzi
510(k) history	3 submissions · 3 cleared · 2025-2026

510k Database - www.510kdatabase.net
Device record: <https://www.510kdatabase.net/k261658/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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