

K260999 LoFric Elle ProApr 24, 2026
29 days to decisionK260999 · Product code: **EZD** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k260999/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Straight (EZD)
Date received	Mar 26, 2026
Decision date	Apr 24, 2026
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Wellspect AB
Location	M?indal, SE
Contact	Emad Ramzi
510(k) history	2 submissions · 2 cleared · 2025-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k260999/> 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 May 13, 2026