

**K250659 LoFric Origo**Sep 26, 2025  
205 days to decisionK250659 · Product code: **EZD** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k250659/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Straight (EZD)
Date received	Mar 5, 2025
Decision date	Sep 26, 2025
Days to decision	205 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Wellspect AB</b>
Location	M?Indal, SE
Contact	Emad Ramzi
510(k) history	2 submissions · 2 cleared · 2025-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250659/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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