FDA 510(k) Premarket Notification

K260999 LoFric Elle Pro

CLEARED

Apr 24, 2026
29 days to decision

K260999 · Product code: **EZD** · Gastroenterology & Urology
Source: 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?lndal, SE
Contact	Emad Ramzi
510(k) history	2 submissions · 2 cleared · 2025-2026