FDA 510(k) Premarket Notification

K260502 Liv Pre-lubricated Intermittent Catheter

CLEARED

Mar 12, 2026
27 days to decision

K260502 · Product code: **EZD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k260502/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Straight (EZD)
Date received	Feb 13, 2026
Decision date	Mar 12, 2026
Days to decision	27 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**HR Healthcare**
Location	York, PA, US
Contact	Colby Wiesman
510(k) history	2 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	**Third Party Review Group, LLC**
Contact	DAVE YUNGVIRT

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov