

K251468 Sleeved IC 3 Family Sleeved IC 3 SWT (name not finalized) Sleeved IC 3 Pocket (name not finalized) Sleeved IC 3 Plus (name not finalized) Sleeved IC 3 Plus Pocket (name not finalized) (N/A)Oct 3, 2025
143 days to decisionK251468 · Product code: **EZD** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k251468/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Straight (EZD)
Date received	May 13, 2025
Decision date	Oct 3, 2025
Days to decision	143 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hollister Incorporated
Location	Libertyville, IL, US
Contact	Sandra Mullen
Website	http://www.hollister.com/
510(k) history	14 submissions · 14 cleared · 2011-2025

Hollister Incorporated specializes in ostomy, continence, and critical care products with a manufacturing facility in Libertyville, US. The company serves patients and healthcare professionals globally across multiple therapeutic areas. Hollister has received FDA 510(k) clearances from total submissions since 2011. The company's regulatory focus centers on Gastroenterology & Urology devices, with the most recent clearance in 2025. This demonstrates sustained innovation and active market engagement in continence care solutions. Recent cleared devices include intermittent c...

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Device record: <https://www.510kdatabase.net/k251468/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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