

K233524 Sleeved IC 2 FamilyMay 3, 2024
184 days to decisionK233524 · Product code: **EZD** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k233524/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Straight (EZD)
Date received	Nov 1, 2023
Decision date	May 3, 2024
Days to decision	184 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Sleeved IC 2 SWT (Name not Finalized); Sleeved IC 2 Plus (Name not Finalized); Sleeved IC 2 Pocket (Name not Finalized); Sleeved IC 2 Plus Pocket (Name not Finalized)

APPLICANT

Company	Hollister Incorporated
Location	Libertyville, IL, US
Contact	Michelle Schiltz-Taing
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/k233524/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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