

K253295 Coude Sleeved ICMay 18, 2026
231 days to decisionK253295 · Product code: **EZD** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k253295/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Straight (EZD)
Date received	Sep 29, 2025
Decision date	May 18, 2026
Days to decision	231 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Coude Plus Sleeved IC

APPLICANT

Company	Hollister Incorporated
Location	Libertyville, IL, US
Contact	Michelle Schiltz-Taing
Website	http://www.hollister.com/
510(k) history	15 submissions · 15 cleared · 2011-2026

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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