FDA 510(k) Premarket Notification

K213575 Female IC (Not Finalized)

CLEARED

Sep 13, 2022
307 days to decision

K213575 · Product code: **EZD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k213575/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Straight (EZD)
Date received	Nov 10, 2021
Decision date	Sep 13, 2022
Days to decision	307 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

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...