

K221593 Cure Ultra Male, Cure Ultra Female, Cure Ultra PlusNov 17, 2022
168 days to decisionK221593 · Product code: **EZD** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k221593/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Straight (EZD)
Date received	Jun 2, 2022
Decision date	Nov 17, 2022
Days to decision	168 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Convatec, Inc.
Location	Skillman, NJ, US
Contact	Courtney Smith
510(k) history	7 submissions · 6 cleared · 2010-2023

REGULATORY CONSULTANT

Consulting firm	MRC Global, LLC
Contact	Dawn Norman

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221593/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026