FDA 510(k) Premarket Notification

CLEARED

K222279 Rusch Intermittent Urethral Catheters

Aug 29, 2022
31 days to decision

K222279 · Product code: **EZC** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k222279/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Coude (EZC)
Date received	Jul 29, 2022
Decision date	Aug 29, 2022
Days to decision	31 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Teleflex Medical**
Location	Fall River, MA, US
Contact	Kelly Breheim
510(k) history	39 submissions · 39 cleared · 2003-2025

Teleflex Medical is an American medical device company headquartered in Wayne, Pennsylvania, with operations in Fall River, US. The company is a major provider of specialty medical devices for critical care and surgical procedures. Teleflex Medical has received FDA 510(k) clearances from total submissions since 2003. The company maintains active regulatory engagement, with the latest clearance in 2025. Its cleared devices span multiple specialties including anesthesiology, general and plastic surgery, cardiovascular, and vascular access systems. The company's product port...