

K173596 Rusch Intermittent Urethral Catheters

Jan 29, 2018
69 days to decision

K173596 · Product code: **EZC** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k173596/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Coude (EZC)
Date received	Nov 21, 2017
Decision date	Jan 29, 2018
Days to decision	69 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Teleflex Medical
Location	Fall River, MA, US
Contact	Amanda Webb
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...