

K973546 KENDALL FAST-CATH PRE LUBRICATED URETHRAL CATHETER

Nov 7, 1997
50 days to decision

K973546 · Product code: **EZD** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k973546/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Straight (EZD)
Date received	Sep 18, 1997
Decision date	Nov 7, 1997
Days to decision	50 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Kendall Healthcare Products Co. Div.Of Tyco Health
Location	Mansfield, MA, US
Contact	PAUL W EVANS
510(k) history	66 submissions · 50 cleared · 1989-1997

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k973546/> 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 25, 2026