FDA 510(k) Premarket Notification

K973546 KENDALL FAST-CATH PRE LUBRICATED URETHRAL CATHETER

CLEARED

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