

K905574 SLIM LINE RETENTION TIP W/ SILICONE RUBBER CUFFJan 24, 1991
43 days to decisionK905574 · Product code: **FGD** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k905574/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention, Barium Enema With Bag (FGD)
Date received	Dec 12, 1990
Decision date	Jan 24, 1991
Days to decision	43 days
Third-party review	No

APPLICANT

Company	E-Z-Em, Inc.
Location	Mchenry, IL, US
Contact	GEORGANNE BROWN
510(k) history	56 submissions · 56 cleared · 1977-2007

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k905574/>; 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 18, 2026