

K930581 E-Z-FLATEJul 1, 1994
512 days to decisionK930581 · Product code: **FCX** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k930581/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Insufflator, Automatic Carbon-dioxide For Endoscope (FCX)
Date received	Feb 4, 1993
Decision date	Jul 1, 1994
Days to decision	512 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k930581/> 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