

K993704 GASTRO-INTESTINAL SYSTEM EN-410WMFeb 11, 2000
101 days to decisionK993704 · Product code: **FDA** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k993704/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enteroscope And Accessories (FDA)
Date received	Nov 2, 1999
Decision date	Feb 11, 2000
Days to decision	101 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Fujinon, Inc.
Location	Washington, DC, US
Contact	GARY ADLER
510(k) history	30 submissions · 30 cleared · 1990-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k993704/> 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 17, 2026