

K951576 FS-34P2, FIBER SIGMOIDOSCOPEJun 29, 1995
86 days to decisionK951576 · Product code: **FAM** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k951576/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sigmoidoscope And Accessories, Flexible/rigid (FAM)
Date received	Apr 4, 1995
Decision date	Jun 29, 1995
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Pentax Precision Instrument Corp.
Location	Mchenry, IL, US
Contact	PAUL SILVA
510(k) history	67 submissions · 67 cleared · 1979-2004

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k951576/> 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