

**K964100 VISION-SCIENCES MODEL SS-U32 ENDO SHEATH
FOR USE WITH THE VSI S-F100 FLEXIBLE FIBEROPTIC
SIGMOIDOSCOPE AND VSI S-V100**Dec 16, 1996
66 days to decisionK964100 · Product code: **FAM** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k964100/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sigmoidoscope And Accessories, Flexible/rigid (FAM)
Date received	Oct 11, 1996
Decision date	Dec 16, 1996
Days to decision	66 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Vision-Sciences, Inc.
Location	Monrovia, CA, US
Contact	PAMELA PAPINEAU
510(k) history	33 submissions · 32 cleared · 1986-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k964100/> 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 June 19, 2026