

K100966 COLONOSCOPE/SIGMOIDOSCOPE SHEATHESAug 3, 2010
117 days to decisionK100966 · Product code: **FDF** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k100966/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colonoscope And Accessories, Flexible/rigid (FDF)
Date received	Apr 8, 2010
Decision date	Aug 3, 2010
Days to decision	117 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sheathing Technologies, Inc.
Location	Morgan Hill, CA, US
Contact	JENNIFER DOWNING
510(k) history	7 submissions · 7 cleared · 1999-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k100966/> 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 16, 2026