FDA 510(k) Premarket Notification

K963344 DISPOSABLE SS-F32 ENDOSHEATH FOR USE WITH THE S-F100 FLEXIBLE FIBEROPTIC SIGMOIDOSCOPE

CLEARED

Nov 21, 1996
87 days to decision

K963344 · Product code: **FAM** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k963344/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sigmoidoscope And Accessories, Flexible/rigid (FAM)
Date received	Aug 26, 1996
Decision date	Nov 21, 1996
Days to decision	87 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.net
Device record: https://www.510kdatabase.net/k963344/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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