

K964326  
Jan 3, 1997

## 510(k) Summary

Pursuant to 512(i)(3)(A) of the Food, Drug and Cosmetic Act, Vision-Sciences is required to submit with this Premarket Notification either an "...adequate summary of any information respecting safety and effectiveness or state that information will be made available upon request of any person." VSI chooses to submit a summary of the safety and effectiveness information. The summary is as follows:

**Trade Name:** VSI Model S-V200 Color Video Sigmoidoscope with Disposable EndoSheath

**Owner/Operator:** Vision-Sciences, Inc.  
6 Strathmore Rd.  
Natick, MA 01760

**Manufacturing Site:** **EndoSheath:**  
Vision-Sciences, Inc.  
6 Strathmore Rd.  
Natick, MA 01760  
Reg. # 1223490

**Endoscope:**  
Vision-Sciences, Inc.  
40 Ramland Rd. South  
Orangeburg, NY 10962  
Reg. #2242464

**Device Generic Name:** Sigmoidoscope and accessories

**Classification:** According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II, Performance Standards (CFR 876.1500).

### Predicate Devices:

1. Vision-Sciences Model S-V100 Video Sigmoidoscope with SS-V32 EndoSheath System (K932843)

Manufactured and Distributed by:  
Vision-Sciences, Inc.  
6 Strathmore Rd.  
Natick, MA 01760

2. Model VS-200 Video Sigmoidoscope (K954704)

Manufactured and Distributed by:  
Welch Allyn Inc.  
4341 State Street Road  
Skaneateles Falls, NY 13153

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**Product Description:**

The VSI Model S-V200 Color Video Sigmoidoscope with Disposable EndoSheath consists of a reusable video sigmoidoscope with a D-shaped cross section containing fiberoptic illumination and imaging bundles and a sterile, disposable, protective sheath containing the air, water and suction/biopsy channels. The sheath is removed and disposed of following each procedure. The EndoSheath intended for use with the proposed sigmoidoscope is currently under FDA review in K964100.

**Indications for Use:**

The proposed VSI Model S-V200 Color Video Sigmoidoscope is intended for use to examine the lower bowel tract, and, using additional accessories, to perform various diagnostic and therapeutic procedures.

**Safety and Performance:**

The following performance testing was presented in support of this submission:

1. Scope Angulation/Cycle Testing (with and without EndoSheath)
2. Scope Resolution (with and without EndoSheath)

Performance testing for the EndoSheath is contained in K964100

No biocompatibility data was presented in support of this Premarket Notification.

**Conclusion:**

Based on the indications for use, technological characteristics, and safety and performance testing, the VSI Model S-V200 Color Video Sigmoidoscope with Disposable EndoSheath has been shown to be safe and effective for its intended use

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