

K964100

P172

DEC 16 1996

Vision Sciences Inc.  
510(k) Premarket Notification

Modified EndoSheath® for VSI Flexible Sigmoidoscopes  
October 10, 1996

## 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:** EndoSheath® for use with the Vision-Sciences  
Model S-F100 and S-V100 Sigmoidoscopes

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

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

**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 874.4760).

**Predicate Devices:** SS-V32 EndoSheath for use with the VSI S-V100 Sigmoidoscope (K932843)  
SS-F32 EndoSheath for use with the VSI S-F100 Sigmoidoscope (K921690)  
EndoSheath for use with the VSI C-F100 Colonoscope (K943895)  
EndoSheath for use with the VSI E-F100 Nasopharyngoscope (K961591)  
EndoSheaths for use with Machida, Pentax and Olympus ENT Scopes  
(K951809)

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

### Product Description:

The EndoSheath for use with the VSI Model S-F100 and S-V100 Sigmoidoscopes consists of a sterile, disposable, protective sheath which covers the patient contact portion of the scope during a clinical procedure. The sheath is removed and disposed of following each procedure.

0140

K964100

p202

Vision Sciences Inc.  
510(k) Premarket Notification

Modified EndoSheath® for VSI Flexible Sigmoidoscopes  
October 10, 1996

**Indications for Use:**

The EndoSheath provides a sterile, disposable protective covering for the scope to be used during endoscopic examination of the sigmoid colon.

**Safety and Performance:**

The following in vitro functional tests were performed on the proposed EndoSheath:

1. Air/Water Tubing Tensile/Elongation Test
2. Distal Head Image Quality Evaluation

Microbial barrier testing using the Phi X 174 bacteriophage was also presented in support of the proposed label claims.

**Conclusion:**

Based on the indications for use, technological characteristics, and safety and performance testing, the EndoSheath for use with the VSI Model S-F100 and S-V100 Sigmoidoscopes has been shown to be safe and effective for its intended use.

2141