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Summary of Safety and Effectiveness

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: SS-F32 EndoSheath® for use with the Vision-Sciences Model S-F100 Sigmoidoscope

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

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-F32 EndoSheath for use with the VSI S-F100 Sigmoidoscope (K921690)
EndoSheath for use with the VSI E-F100 Nasopharyngoscope (K961591)
EndoSheath for Use with the VSI C-F100 Colonoscope (K943895)
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 SS-F32 EndoSheath for use with the VSI Model S-F100 Sigmoidoscope 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.

Indications for Use:

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

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Safety and Performance:

The following in vitro functional tests were performed on the proposed SS-F32 EndoSheath for use with the VSI Model S-F100 Sigmoidoscope:

1. Sheath Functional and Performance Test
2. Sheath Tensile Test

Microbial barrier testing using live polio virus as well as 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 SS-F32 EndoSheath for use with the VSI Model S-F100 Sigmoidoscope has been shown to be safe and effective for its intended use.