

K961591

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: Endosheath® for use with the Vision-Sciences
Model E-F100 Nasopharyngoscope

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: Nasopharyngoscope 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:

EndoSheaths for use with the Machida Model ENT-4L, Olympus
Model ENF Type 3P, Pentax Model FNL-10S and Pentax Model FNL-13S endoscopes
(K921244, K925421, K933247)

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

Product Description:

The VSI EndoSheath for use with the VSI Model E-F100 Nasopharyngoscope 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 upper airway, vocal chords, and/or nasal passages.

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Safety and Performance:

The following in vitro functional tests were performed on the proposed Endosheath for use with the VSI Model E-F100 Nasopharyngoscope:

1. Functional and Burst Test
2. Scope Angulation (With and Without Sheath)
3. Scope OD (With and Without Sheath)
4. Sheath Longitudinal and Radial Strain when Loaded on Scope
5. Light Transmittance
6. Field of View
7. Scope Resolution (With and Without Sheath)

The following biocompatibility data was presented in support of this Premarket Notification:

1. Irritation
2. Sensitization
3. Cytotoxicity
4. Acute Systemic Toxicity
5. Hemolysis
6. Implantation

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 EndoSheath for use with the VSI Model E-F100 Nasopharyngoscope has been shown to be safe and effective for its intended use.

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