

K963795

DEC 23 1996

Vision Sciences Inc.
510(k) Premarket Notification

Flexible Fiberoptic Bronchoscope with Disposable EndoSheath®
September 20, 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: VSI Model B-F100 Bronchoscope with Model BS-F21 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: Bronchoscope and accessories

Classification: According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II, Performance Standards (CFR 874.4680).

Predicate Devices:

1. Model BF-3C20 Bronchoscope

Manufactured and Distributed by:
Olympus Corp.
4 Nevada Dr.
Lake Success, NY 11042

2. Model FB-10X Bronchoscope, Model FB-18RX Bronchoscope and Model FI-10P Intubation Scope

Manufactured and Distributed by:
Pentax Precision Instrument Corp.
30 Ramland Road.
Orangeburg, NY 10962

3. Model SF-100 Flexible Fiberoptic Sigmoidoscope and Disposable EndoSheath (K921690)

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

4. Model SV-100 Flexible Video Sigmoidoscope and Disposable EndoSheath (K932843)

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

5. Protective Sheath for use with the VSI Model E-F100 ENT endoscope (K961591)

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

6. Protective Sheath for use with the Machida Models ENT-3L and ENT-4L, Olympus Model ENF Type 3P, Pentax Model FNL-10S and Pentax Model FNL-13S endoscopes (K950809)

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

Product Description:

The VSI Model B-F100 Bronchoscope with BS-F21 Disposable EndoSheath consists of a reusable bronchoscope with a D-shaped cross section containing fiberoptic illumination and imaging bundles and a sterile, disposable, protective sheath containing the suction/biopsy channel. The sheath is removed and disposed of following each procedure.

Indications for Use:

The Vision Sciences (VSI) Bronchoscope and Disposable Sheath System will be used for diagnostic examination of the inside of the trachea or windpipe and other major air passages of the lungs. It may also be used to gather specimens and to find and remove foreign objects in the lungs.

Safety and Performance:

The following in vitro functional tests were performed on the proposed VSI Model B-F100 Bronchoscope with BS-F21 Disposable EndoSheath:

1. System Functional Testing
2. System Cycle Testing
3. Sheath Burst Testing

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

1. Irritation
2. Sensitization
3. Cytotoxicity
4. Acute Systemic Toxicity

Microbial barrier testing was also included.

Conclusion:

Based on the indications for use, technological characteristics, and safety and performance testing, the VSI Model B-F100 Bronchoscope with Model BS-F21 Disposable EndoSheath has been shown to be safe and effective for its intended use.