3/31/99

K990354

510(k) Summary

Trade Name: **Vision-Sciences EndoSheaths® for use with Flexible ENT Scopes**

Sponsor: Vision-Sciences, Inc.
9 Strathmore Road
Natick, MA 01760
Resistration #1223490

Device Generic Name: Protective sheath for endoscope

Classification: According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II.

Predicate Devices:
K950809 - Modified ENT EndoSheaths®
K961591 - EndoSheath® for E-F100 ENT Scope
K933247 - ENT EndoSheath®
K925421 - ENT EndoSheath®
K921244 - ENT EndoSheath®

Manufactured by:
Vision-Sciences, Inc.
9 Strathmore Road
Natick, MA 01760

Product Description: The devices described in this 510(k) are sterile, disposable, sheaths designed to fit a variety of nasolaryngo-pharyngoscopes. The use of an EndoSheath® eliminates the need for high-level disinfection of the scope following each procedure.

Indications for Use:
The Vision-Sciences EndoSheaths® are indicated for use as a protective covering for the scope during endoscopic examination of the upper airway, vocal chords and/or nasal passages.

Safety and Performance:
This submission is a Special 510(k): Device Modification as described in FDA's guidance document entitled "The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications." In support of this 510(k), Vision-Sciences has provided certification of compliance to 21 CFR 820.30 Design Control requirements, and a description of the internal Risk Analysis procedure. Validation testing including microbial barrier testing, tensile/elongation testing, leak testing, sheathed scope articulation testing and sheathed scope image quality evaluation is included in Design Validation and Verification planning.

Conclusion:
Based on the indications for use, technological characteristics, and comparison to predicate devices, the modified EndoSheaths® for use with Flexible ENT scopes have been shown to be safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 31 1999

Pamela Papineau
Consultant to Vision-Science, Inc.
Vision Sciences, Inc.
6 Strathmore Road
Natick, MA 01760

Re: K990354
Trade Name: EndoSheath ® for use with Flexible ENT Scope
Regulatory Class: II
Product Code: 77 EOB
Dated: March 16, 1999
Received: March 17, 1999

Dear Ms. Papineau:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K990354

Device Name: EndoSheath® for use with Flexible ENT Scopes

Indications for Use:

The EndoSheath® provides a sterile, disposable protective covering for the scope to be used during flexible endoscopic examination of the upper airway, vocal chords and/or nasal passages.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the -Counter Use ____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K990354
Karen Bohn (for HLS)