K024095

JAN 0 9 2003

510(k) Summary

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

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

Device Generic Name: Disposable sheath for flexible ENT scopes

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

Predicate Devices: **K990354 – Modified EndoSheath® for Flexible ENT Scopes**
K012543 – EndoSheath® System for Flexible ENT Scopes
K021344 – EndoSheath® System for Flexible Fiberoptic Bronchoscope
Manufactured by:
Vision-Sciences, Inc.
9 Strathmore Road
Natick, MA 01760

Product Description: The device system described in this 510(k) consists of modified sterile, disposable sheaths designed to fit various models of flexible fiberoptic ENT scopes. The use of an EndoSheath® eliminates the need for high-level disinfection of the scope following each procedure. The disposable sheath features a specially designed working channel that allows a "visual-only" diagnostic flexible ENT scope to be utilized as a multi-purpose diagnostic and therapeutic device

Indications for Use:
The EndoSheath® System provides a sterile, disposable protective covering for the scope to be used during flexible endoscopic examination of the upper airway, vocal cords 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, sheath tensile/elongation testing and sheath leak/burst testing is included in Design Validation and Verification planning.

Conclusion:
Based on the indications for use, technological characteristics, and comparison to predicate devices, the modified VSI EndoSheath® System for use with Flexible ENT Scopes has been shown to be safe and effective for its intended use.

Figure D.2
Design/Materials Comparison

Characteristic	Proposed Modified VSI Channel ENT EndoSheath® System (Current Submission)	Currently Marketed, Unmodified VSI ENT EndoSheath® System (K990354, K012534)	Currently Marketed, Unmodified VSI Bronchoscope EndoSheath® System (K021344)
Sheath material	Same as VSI predicate devices	Thermoplastic elastomer	Thermoplastic elastomer
Window material	Same as VSI predicate devices	Thermoplastic polymer	Thermoplastic polymer
Luer connector material	Same as VSI predicate devices	N/A – no luer connector	Thermoplastic polymer
Proximal connector material	Same as VSI predicate devices	Thermoplastic polymer	Thermoplastic polymer
Working channel ID	2.1 mm	N/A – no working channel	2.1 mm
Working channel materials	Same as VSI predicate devices	N/A – no working channel	Thermoplastic polymer
UV cure adhesives	Same family of adhesives as VSI predicate devices	Yes	Yes
Support tube material	Identical to VSI predicate devices	Thermoplastic polymer	Thermoplastic polymer
Microbial barrier claim	Yes	Yes	Yes
Mating scope models	Vision-Sciences ENT-2000/E-F100 Olympus ENF-P4/P3/P2 Pentax VNL-1330 and FNL-10S/10BS/10P2/10RP3/13S Welch Allyn RL-150 Karl Storz 11101RP/11101RP1	Vision-Sciences ENT-2000/E-F100 Olympus ENF-P4/P3/P2 Pentax VNL-1330 and FNL-10S/10BS/10P2/10RP3/13S Welch Allyn RL-150 Karl Storz 11101RP/11101RP1	VSI Bronchoscope
Sheath installation method	Slides on and off (no vacuum/pressure source required)	Slides on and off (no vacuum/pressure source required)	Slides on and off (no vacuum/pressure source required)
Minimum sheath wall thickness	.002"	.002"	.002"
Indications for Use	For use in flexible, endoscopic examination of the upper airway, vocal cords and/or nasal passages.	For use in flexible, endoscopic examination of the upper airway, vocal cords and/or nasal passages.	Is used during flexible endoscopic examination of the trachea and other major passages of the lungs, to gather specimens, and/or to find and endoscopically remove foreign objects from the lungs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 0 9 2003

Vision-Sciences, Inc.
c/o Pamela Papineau, RAC
Delphi Medical Device Consulting, Inc.
5 Whitcomb Avenue
Ayer, MA 01432

Re: K024095
Trade/Device Name: Endosheath System for use with Flexible ENT Scopes
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOB
Dated: December 6, 2002
Received: December 12, 2002

Dear Ms. Papineau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4692. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

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

510(k) Number (if known): K024095

Device Name: EndoSheath® System for use with Flexible ENT Scopes

Indications for Use:

The EndoSheath® System provides a sterile, disposable protective covering for the scope to be used during flexible endoscopic examination of the upper airway, vocal cords 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 Ear,
Nose and Throat Devises

510(k) Number K024095