K 031790

JUL 2 2003

510(k) Summary

Trade Name: **Vision-Sciences Slide-On™ EndoSheath® System for Sensory Testing**

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

Device Common Name: Endoscope and Accessories - 77EOB

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

Predicate Devices:

K990354 – Slide-On EndoSheath® for Flexible ENT Scopes
K012543 – EndoSheath® System for Flexible ENT Scopes
K024095 – Slide-On™ EndoSheath® System for Flexible ENT Scopes
Manufactured by:
Vision-Sciences, Inc.
9 Strathmore Road
Natick, MA 01760

K964815 – AP-4000 Air Pulse Sensory Stimulator
Manufactured by:
Pentax Precision Instrument Corp.
3117 Commerce Parkway
Miramar, FL 33025

Product Description: The device system described in this 510(k) consists of a sterile, single use protective sheath for use with the VSI ENT-2000 scope.

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. The System may also be used in conjunction with the Pentax AP-4000 Air Pulse Sensory Stimulator to elicit Laryngeal Closure Reflex (Swallow) and to measure the sensory discrimination threshold at which the reflex occurs in the area of the Upper Airway innervated by the Superior Laryngeal Nerve.

Safety and Performance: Substantial equivalence for the new device was based on design characteristics, comparison to legally marketed predicate devices, and performance testing. Performance testing included sheath burst/leak testing, sheath tensile/elongation testing, sheathed scope articulation testing and air pulse testing.

Conclusion: Based on the indications for use, technological characteristics, performance testing and comparison to predicate devices, the proposed VSI Slide-On™ EndoSheath® System for Sensory Testing has been shown to be safe and effective for its intended use.

VSI Trans-Nasal Esophagoscope with EndoSheath® System
Substantial Equivalence Comparison

Characteristic	Proposed VSI Slide-On™ EndoSheath® System for Sensory Testing (Current Submission)	Currently Marketed VSI ENT-2000 with EndoSheath® System (K990354, K012534, K024095)	Pentax ENL-Series ENT Scopes for use with AP-4000 Air Pulse Sensory Stimulator (K964815)
Sheath material	Same as VSI predicate devices	Thermoplastic elastomer	N/A – No sheath
Window material	Same as VSI predicate devices	Thermoplastic polymer	N/A – No sheath
Luer connector material	Same as VSI predicate devices	N/A – no luer connector	N/A – No sheath
Proximal connector tubing material	Same as VSI predicate devices	Thermoplastic polymer	N/A – No sheath
Air channel ID	N/A – no working channel	N/A – no working channel	1.2 mm
Adhesives	Same as VSI predicate devices	UV curable	Unknown
Microbial barrier claim	Yes	Yes	N/A – No sheath
Sheath installation method	Slides on and off (no vacuum/pressure source required)	Slides on and off (no vacuum/pressure source required)	N/A – No sheath
Sheath length	12"	12"	N/A – No sheath
Minimum sheath wall thickness	.002"	.002"	N/A – No sheath
Sheath Packaging	Tyvek/Mylar pouch	Tyvek/Mylar pouch	N/A – No sheath
Scope working length (with sheath)	300 mm	300 mm	300 mm
Scope insertion tube OD (distal tip)	4.1 mm (w/sheath)	3.6 mm	3.4 mm
Articulation (Up/Down)	90°/90° (sheathed scope)	135°/135° (sheathed scope)	130°/130°
Angle of View	75°	75°	75°
Depth of Field	3 – 50 mm	3 – 50 mm	Unknown

Characteristic	Proposed VSI Slide-On™ EndoSheath® System for Sensory Testing (Current Submission)	Currently Marketed VSI ENT-2000 with EndoSheath® System (K990354, K012534, K024095)	Pentax FNL-Series ENT Scopes for use with AP-4000 Air Pulse Sensory Stimulator (K964815)
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. The System may also be used in conjunction with the Pentax AP-4000 Air Pulse Sensory Stimulator to elicit Laryngeal Closure Reflex (Swallow) and to measure the sensory discrimination threshold at which the reflex occurs in the area of the Upper Airway innervated by the Superior Laryngeal Nerve.	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.	To elicit Laryngeal Closure Reflex (Swallow) and to measure the sensory discrimination threshold at which the reflex occurs in the area of the Upper Airway innervated by the Superior laryngeal Nerve. The structures being stimulated in the area of the Upper Airway innervated by the Superior Laryngeal Nerve are: the Left and Right Anterior Wall of the Pyriform Sinus and the Left and Right Aryepiglottic Folds. The device is intended to be used with a legally marketed endoscope compatible with the AP-4000, introduced per nasally in Adult and Pediatric patient populations with suspected Dysphagia

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 2003

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

Re: K031790
Trade/Device Name: Slide-On™ EndoSheath System® for Sensory Testing
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOB
Dated: June 9, 2003
Received: June 10, 2003

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) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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, 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): K031790

Device Name: Slide-On™ EndoSheath® System for Sensory Testing

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. The System may also be used in conjunction with the Pentax AP-4000 Air Pulse Sensory Stimulator to elicit Laryngeal Closure Reflex (Swallow) and to measure the sensory discrimination threshold at which the reflex occurs in the area of the Upper Airway innervated by the Superior Laryngeal Nerve.

(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 K031790