K071903

510(k) Summary

Owner's Name:	Vision-Sciences, Inc.
Address:	9 Strathmore Road Natick, MA 01760
Telephone Number:	(508) 650-9971
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Contact Person:	Charles Iannaccone; QA/RA Manager

AUG - 2 2007

Subject Device Name:	EndoSheath® Systems for use with VSI Flexible TNE Scope
Common/Usual Name:	Protective sheath for use with flexible endoscope
Product Codes:	EOX
FDA Regulations:	21 CFR 874.4710
Device Classification:	Class II

Predicate Device Name:	EndoSheath® Systems for use with VSI Flexible TNE Scope
Common/Usual Name:	Protective sheath for use with flexible endoscope
Product Codes:	EOX
FDA Regulations:	21 CFR 874.4710
Device Classification:	Class II
Premarket Notification:	K031786

Device Description
The VSI EndoSheath® Systems are sterile, single-use protective sheath systems, with or without a working channel, that are intended to cover the entire insertion tube of the flexible endoscope.

Intended Use
The flexible trans-nasal esophagoscope with sheath system is intended for use in endoscopic access and examination of the larynx, esophagus and gastro-esophageal junction. The device may also be used to assist intubation.

Performance Testing
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. V & V activities, including sheath functional and performance testing, was addressed through Design Validation and Verification planning.

Conclusion
Based on the indications for use, technological characteristics, performance testing and comparison to predicate devices, the modified VSI EndoSheath® Systems for use with the VSI flexible TNE scope 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

AUG - 2 2007

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

Re: K071903
Trade/Device Name: EndoSheath® Systems for use with VSI Flexible TNE Scope
Regulation Number: 21 CFR 874.4710
Regulation Name: Esophagoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOX
Dated: July 6, 2007
Received: July 10, 2007

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M. B. Eydelman, MD

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K071903

Device Name: EndoSheath® Systems for use with VSI Flexible TNE Scope

Indications for Use:

The flexible trans-nasal esophagoscope with EndoSheath® System is intended for use in endoscopic access and examination of the larynx, esophagus and gastro-esophageal junction. The device may also be used to assist intubation.

Prescription Use __X__ OR Over-the -Counter Use ____

(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K071903