K100125

510(k) Summary

Date Prepared (21 CFR 807.92(a)(1): January 15, 2010

Owner's Name (21 CFR 807.92(a)(1):

	Vision-Sciences, Inc.
Address:	40 Ramland Road South Orangeburg, NY 10962
Telephone Number:	(845) 365-0600
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Contact Person:	Lillian Quintero; Director QA/RA

FEB 25 2010

Trade Name, Common Name, Classification (21 CFR 807.92(a)(2))

Subject Device Name:	Vision Sciences Model ENT-3000 Flexible Nasopharyngoscope with BLS-1000 Battery Powered LED
Common/Usual Name:	Flexible ENT Scopes
Product Codes:	EOB
FDA Regulations:	21 CFR 874.4760
Device Classification:	Class II

Predicate Device Names (21 CFR 807.92(a)(3))

	Vision Sciences - Model ENT-3000 Portable Flexible Nasopharyngoscope with BLS-1000 Battery Powered LED Light Source (K050972)
	OPTIM Incorporated – "PLS" Portable Light Source (K091829)
Common/Usual Name:	Endoscope and Accessories
Product Codes:	EOB, NTN
FDA Regulations:	21 CFR 874.4760, 21 CFR 876.1500
Device Classification:	Class II
Premarket Notification:	K050972, K091829

Device Description
The ENT-3000 Scope and BLS-1000 offers optimal portability for endoscopic viewing. LED based illumination provides bright white light for endoscopic viewing.

Intended Use
The Flexible ENT scope is indicated for use during flexible 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 – Alternative 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 light output, operating temperature and electrical safety testing was included in Design Validation and Verification planning.

Conclusion
Based on the indications for use, technological characteristics, performance and electrical testing and comparison to predicate devices, the VSI ENT-3000 has been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Vision-Sciences, Inc.
% Ms Stacie Geffner-Atiya
40 Ramland Road South
Orangeburg, NY 10962

FEB 25 2010

Re: K100125
Trade/Device Name: Vision Sciences Flexible ENT Scope
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOB
Dated: January 8, 2010
Received: January 21, 2010

Dear Ms Stacie Geffner-Atiya:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

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.
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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K100125

Device Name: Vision Sciences Flexible ENT Scope

Indications For Use:

The Vision Sciences' Flexible ENT Scope is intended for flexible endoscopic examination of the upper airway, vocal chords and/or nasal passages.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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