K040984

APR 2 7 2004

510(k) Summary

Trade Name: **Vision Sciences Model ENT-2000V Flexible Nasopharyngo-Laryngoscope**

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

Device Generic Name: Flexible ENT scopes

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

Predicate Devices: **K942265 – Flexible ENT Scope**
K990354 – Modified EndoSheath® for Flexible ENT Scopes
Manufactured by:
Vision-Sciences, Inc.
9 Strathmore Road
Natick, MA 01760

Product Description: The device described in this 510(k) consists of modified flexible fiberoptic ENT scope. The scope has been modified to include an integral camera module and camera control unit.

Indications for Use:
The 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 - 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 scope image quality evaluation, focal length, resolution, distortion, reprocessing effects and electrical safety 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 Flexible ENT Scope has been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 27 2004

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

Re: K040984
Trade/Device Name: Vision Sciences Model ENT-2000V Flexible Nasopharyngo-Laryngoscope
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (flexible or rigid) and accessories.
Regulatory Class: Class II
Product Code: EOB
Dated: April 8, 2004
Received: April 15, 2004

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

Enclosure

510(k) Number (if known): K040984

Device Name: Vision Sciences Model ENT-2000V Flexible Nasopharyngo-Laryngoscope

Indications for Use:

The VSI Model ENT-2000V Flexible Nasopharyngo-Laryngoscope is intended for 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 X AND/OR Over-the -Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart D)

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

510(k) Number K040984