510(k) Summary K053560

Trade Name: **Vision-Sciences Flexible Cystoscope with EndoSheath® System**

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

Device Common Name:
Cystoscope with sheath

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

Predicate Devices:
K040215 – VSI CST-Dx Slide-On Cystoscope Sheath for use with VSI Flexible Cystoscope
K031786 – VSI TNE-BxD Slide-On EndoSheath® for use with VSI Flexible Trans-Nasal Esophagoscope

Manufactured by:
Vision-Sciences, Inc.
9 Strathmore Road
Natick, MA 01760

Product Description: The device system described in this 510(k) consists of a flexible, fiberoptic cystoscope and sterile, single use protective sheath.

Indications for Use:
The Vision-Sciences Flexible Fiberoptic Cystoscope with EndoSheath® System is indicated for use in endoscopic access and examination of the lower urinary tract including the bladder and, using additional accessories, to perform various diagnostic and therapeutic procedures.

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. V & V activities included modified device labeling, and 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 proposed modified EndoSheath® System for use with VSI Flexible Cystoscope 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

MAR 16 2006

Vision-Sciences, Inc.
% Ms. Pamela Papineau, RAC
Consultant
Delphi Medical Device Consulting, Inc.
5 Whitcomb Avenue
AYER MA 01432

Re: K053560
Trade/Device Name: Modified EndoSheath® System for VSI Flexible Cystoscope
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FAJ
Dated: February 27, 2006
Received: March 1, 2006

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 (Premarket Approval), 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 one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K053560

Device Name: Modified EndoSheath® System for VSI Flexible Cystoscope

Indications for Use:

For endoscopic access and examination of the lower urinary tract including the bladder and, using additional accessories, to perform various diagnostic and therapeutic procedures.

Prescription Use X AND/OR Over-the -Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart D)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K053560