510(k) Summary

K072180

DEC 18 2007

Owner's Name:	Vision-Sciences, Inc.
Address:	40 Ramland Road South Orangeburg, NY 10962
Telephone Number:	(845) 365-0600
Fax Number:	(845) 365-0620
Contact Person:	Lillian Quintero; Director QA/RA
Subject Device Name:	Flexible Video Cystosope with Digital Video Processor and Disposable EndoSheath® Systems
Common/Usual Name:	Flexible video endoscopes with video processor and disposable sheaths
Product Codes:	FAJ
FDA Regulations:	21 CFR 876.1500
Device Classification:	Class II
Predicate Device Name:	Flexible Fiberoptic Cystoscope with EndoSheath® Systems
Common/Usual Name:	Flexible fiberoptic cystoscope with sheaths and accessories
Product Codes:	FAJ
FDA Regulations:	21 CFR 876.1500
Device Classification:	Class II
Premarket Notification:	K040215 / K053560

Device Description
The VSI flexible endoscope is a flexible endoscope with connections to a video processor and display monitor. The 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 videoscope. The digital video processors are used with the flexible videoscope for image visualization and capture.

Intended Use
The flexible video cystoscope with digital video processor and disposable sheath system is intended 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.

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 biocompatibility testing, scope/sheath/processor system functional and performance testing, and software validation was addressed through comprehensive Design Validation and Verification planning.

Conclusion
Based on the indications for use, technological characteristics, performance testing and comparison to predicate devices, the VSI flexible video cystoscope with digital video processors and disposable EndoSheath® Systems 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

DEC 1 8 2007

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

Re: K072180
Trade/Device Name: Video Cystoscope with Digital Video Processor and EndoSheath® Systems
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FAJ, FED and FFS
Dated: November 16, 2007
Received: November 20, 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 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" (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,

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): K072180

Device Name: Flexible Video Cystoscope with Digital Video Processor and Disposable EndoSheath® Systems

Indications for Use:

The flexible video cystoscope with EndoSheath® System is intended 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.

The digital video processor is intended for use with the VSI flexible video scope.

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 Reproductive, Abdominal and Radiological Devices
510(k) Number K072180