K071127

510(k) Summary

Trade Name:	**Vision-Sciences Flexible Cystoscope with EndoSheath® System** (with additional Hysteroscope Indications for Use)
Sponsor:	Vision-Sciences, Inc. 9 Strathmore Road Natick, MA 01760 Registration #1223490
Device Common Name:	Hysteroscope with sheath
Regulation & Product Code:	21 CFR 884.1690 / HIH
Classification:	According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II.
Predicate Devices:	**K040215 & K053560 – VSI Flexible Cystoscope with Slide-On EndoSheath® System** **Manufactured by:** Vision-Sciences, Inc. 9 Strathmore Road Natick, MA 01760 **Olympus HYF-P Flexible Fiberoptic Hysteroscope (K891451)** **Olympus HYF-1T Flexible Fiberoptic Hysteroscope**

NOV 1 6 2007

Product Description: The device system described in this 510(k) consists of a flexible, fiberoptic endoscope and sterile, single use protective sheath. This 510(k) adds a hysteroscopy indication to the currently marketed VSI Cystoscope with EndoSheath® System.

Indications for Use:
The CST-2000A and Slide-On® EndoSheath® System provides for endoscopic access and examination of the lower urinary tract including the bladder, and using additional accessories, to perform various diagnostic and therapeutic procedures.

The CST-2000A and Slide-On® EndoSheath® System is used to permit direct viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and therapeutic/surgical procedures.

Note: The CST-2000A and Slide-On Endosheath System is not indicated for electrosurgical procedures.

Safety and Performance:
Substantial equivalence for scope and sheath for hysteroscopy indications was based on design characteristics, comparison to legally marketed predicate devices, and performance testing. Performance testing included sheath burst/leak testing, sheath tensile/elongation testing, sheathed scope articulation testing, sheathed scope image quality evaluation and scope cycle testing.

Conclusion:
Based on the indications for use, technological characteristics, performance testing and comparison to predicate devices, the proposed scope and sheath system 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

NOV 1 6 2007

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

Re: K071127
Trade Name: Flexible Hysteroscope with EndoSheath® System
Regulation Number: 21 CFR §884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: HIH
Dated: October 26, 2007
Received: October 30, 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): K071127

Device Name: Flexible Hysteroscope with EndoSheath® System

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Prescription Use __X__ AND/OR Over-the -Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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 K071127