K022445

JAN 2 4 2003

SMDA 510(k) SUMMARY

This summary of 510(k safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR Section 807.92.

A. Submitter's Name, Address, Phone and Fax Number

1. Applicant:
Olympus Optical Co., Ltd.
2-3-1 Shinjuku Monolis Nishi-shinjuku
Shinjuku-ku, Tokyo, Japan, 163-0914

2. Registration No. 8010047

3. Initial Importer
Olympus America Inc.
Two Corporate Center Drive
Melville, NY 11747-3157

4. Registration No. 2429304

5. Contact Person
Laura Storms-Tyler
Director, Regulatory Affairs
Olympus America Inc.
Two Corporate Center Drive
Melville, NY 11747-3157
Tel (631)-844-5688
Fax(631)-844-5416

B. Device Name, Common Name

1. Trade/Proprietary Name and Common Name

Trade Name: VISERA HYSTEROVIDEOSCOPE OLYMPUS HYF TYPE V
Common Name: Hysteroscope

2. Class, Classification Number and Classification Name

Classification Number	Classification Name	Class
21 CFR 884.1690	Hysteroscope and accessories	II
21 CFR 876.1500	Endoscopes and accessories	II

3. Identification of Legally Marketed Devices Which we Claim Substantial Equivalence

The following listed devices are seem to be as predicate devices in consideration of its characteristic and the following table shows regulatory history.

Model	Device Description & 510(k)#/ Date of Cleared	Manufacturer	Class
BF-240	#K963033	Olympus Optical Co.,	II
Olympus HYF-P Flexible hysterofiberscope	#K891451	Olympus Optical Co.,	II

D. Summary Description of the Device

1. Summary

This subject device is videoscope used for diagnosis within the uterus.
New type of CCD is lead to be more easier observation and diagnosis. In HYF-V, a light guide connector and a video connector are separated each other. The light guide connector is to connect with a light source and the video connector is with a video system center.

2. Design

"HYF-V" has been designed, manufactured and tested in compliance with voluntary safety standards.
It meets the requirement of IEC60601-1, IEC60601-1-1, IEC60601-1-2, IEC60601-2-18.

3. Materials

There are no new patient contacting materials. All of patient contacting materials are cleared by previous 510(k). And all materials have been confirmed with ISO 10993-1.

4. Intended Use of the device

This instrument has been designed to be used with an Olympus video system center, light source, documentation equipment, display monitor, and other ancillary equipment for endoscopic diagnosis within the uterus, including:

- Abnormal uterine bleeding
- Evaluation of abnormal hysterosalpingogram
- Evaluation of abnormal ultrasound image
- Infertility and pregnancy wastage
- Pelvic pain

5. Technological Characteristics

This endoscope does not have special technological characteristics compared to the existence videoscope such as GI tract bronchial apprication.

6. Reason for not requiring

Compare to the predicate device, this subject device "HYF-V" does not incorporate any significant change for its safety and efficacy to the predicate device.
Observation within uterus has been spread, therefore clinical date is not necessary for its evaluation of safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 4 2003

Olympus Optical Co., Ltd.
% Ms. Laura Storms-Tyler
Director, Regulatory Affairs
and Quality Assurance
Olympus America, Inc.
Two Corporate Center Drive
MELVILLE NY 11747-3157

Re: K022445
Trade/Device Name: Visera Hysterovideoscope
Olympus HYF Type V
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: 85 HIH
Dated: November 12, 2002
Received: November 13, 2002

Dear Ms. Storms-Tyler:

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 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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,

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

OLYMPUS

Indications for Use Statement

510(k) Number(if known): K022445

Device Name: VISERA HYSTEROVIDEOSCOPE OLYMPUS HYF TYPE V

Indications for Use :

This instrument has been designed to be used with an Olympus video system center, light source, documentation equipment, display monitor, and other ancillary equipment for endoscopic diagnosis within the uterus, including:

- Abnormal uterine bleeding
- Evaluation of abnormal hysterosalpingogram
- Evaluation of abnormal ultrasound image
- Infertility and pregnancy wastage
- Pelvic pain

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use / OR Over-The-Counter Use

(Prescription 21 CFR 801.109)

Nancy C Brogdon (Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022445