September 2, 2022

Olympus Medical Systems Corporation
% Gary Brennan
Regulatory Program Manager
Olympus Corporation of the Americas
800 West Park Drive
Westborough, MA 01581

Re: K221557
Trade/Device Name: VISERA HYSTEROVIDEOSCOPE OLYMPUS HYF TYPE V (HYF-V)
Regulation Number: 21 CFR§ 884.1690
Regulation Name: Hysteroscope and Accessories
Regulatory Class: II
Product Code: HIH
Dated: August 9, 2022
Received: August 11, 2022

Dear Gary Brennan:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jason R. Roberts, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221557

Device Name
VISERA HYSTEROVIDEOSCOPE OLYMPUS HYF TYPE V (HYF-V)

Indications for Use *(Describe)*
VISERA HYSTEROVIDEOSCOPE OLYMPUS HYF TYPE V 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. Do not use the instrument for any purpose other than its intended use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

For

VISERA HYSTEROVIDEOSCOPE OLYMPUS HYF TYPE V (HYF-V)

General Information

Applicant:	OLYMPUS MEDICAL SYSTEMS CORP. 2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan 192-8507 Phone: (+81) 42-642-2694 Fax: (+81) 42-642-2307 Establishment Registration Number: 8010047
Manufacturer:	Shirakawa Olympus Co., Ltd. 3-1 Okamiyama, Odakura, Nishigo-mura, Nishishirakawa-gun, Fukushima 961-8061, Japan Phone: (+81) 248-27-2239 Fax: (+81) 248-27-2429 Establishment Registration Number: 3002808148 Aizu Olympus Co., Ltd. 500 Muranishi, Niidera, Monden-machi, Aizuwakamatsushi, Fukushima 965-8520, Japan Phone: (+81) 172-52-8511 Fax: (+81) 172-52-8515 Establishment Registration Number: 9614641
510(k) Submitter:	Olympus Corporation of the Americas 3500 Corporate Parkway Center Valley, PA 18034-0610
Establishment Registration Number:	2429304
Contact Person:	Gary Brennan Regulatory Affairs Program Manager Mobile : (315) 877-7298 Email : Gary.Brennan@olympus.com
Date Prepared:	September 1, 2022

Device Description

Classification Name:	Hysteroscope and accessories
Generic/Common Name:	Hysteroscope
Trade Name:	VISERA HYSTEROVIDEOSCOPE OLYMPUS HYF TYPE V (HYF-V)
Model Number:	HYF-V
Regulation Number:	884.1690
Regulatory Class:	Class II
Product Codes:	HIH
Review Panel:	Obstetrics/Gynecology

Table 15-1. Predicate Device

Predicate Device	510(k) No.
VISERA HYSTEROVIDEOSCOPE OLYMPUS HYF TYPE V	K022445

The predicate device has not been subject to a design-related recall.

Product Description

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.

Comparison of Technological Characteristics

Table 5-1 compares HYF-V to the predicate device with respect to intended use, technological characteristics, and principle of operation, providing detailed information regarding the basis for the determination of substantial equivalence.

Table 5-1: Comparison of the technological characteristics of HYF-V to predicate device

Comparator	Subject Device	Predicate Device
Regulatory		
Device Name (Model)	Same as predicate	Visera Hysterovideoscope (HYF-V)
Regulatory Decision	Same as predicate	K022445
Product Code	Same as predicate	HIH
Regulation Number	Same as predicate	884.1690
Regulation Name	Same as predicate	Hysteroscope and accessories
Indications for use	VISERA HYSTEROVIDEOSCOPE OLYMPUS HYF TYPE V has been designed to be used with an Olympus video	This instrument has been designed to be used with an Olympus video system center, light source, documentation equipment, display monitor, and

Comparator	Subject Device	Predicate Device
	system center, light source, documentation equipment, display monitor, and other ancillary equipment for endoscopic diagnosis within the uterus. Do not use the instrument for any purpose other than its intended use.	other ancillary equipment for endoscopic diagnosis within the uterus, including: • Abnormal uterine bleeding • Amenorrhea • Evaluation of abnormal hysterosalpingogram • Infertility and pregnancy wastage • Pelvic pain
Optical system parameters		
Field of View	Same as predicate	120°
Direction of View	Same as predicate	0° (Forward viewing)
Depth of Field	Same as predicate	2-50mm (for all compatible light sources)
Imaging System		
Noise	OTV-S190/ CLV-S190	OTV-S7V/ CLV-S40
Insertion Section		
Insertion Flexible Tube Outer Diameter	Same as predicate	3. 6mm
Distal End	Same as predicate	3.8 mm
Working Length	Same as predicate	240 mm
Instrument Channel		
Channel Inner Diameter	Same as predicate	1.2 mm
Bending Section		
Angulation Range	Same as predicate	Up 100° / Down 100°
Connection to Light Source		
Configuration	Light Guide (LG) cable is not detachable	Light Guide (LG) cable is not detachable
Venting Connector		
Position	Same as predicate	On LG connector
Sterilization		
EO	Same as predicate	Available
Others		
Total length	Same as predicate	520mm
Suction Function	Same as predicate	Not provided
Compatible Video System Center/Light Source/Monitor/Reprocessor		
Compatible Video System Center	VISERA ELITE video system center, OTV-S190 (K111425)	VISERA video system center, OTV-S7V (K051645)
Compatible Light Source	VISERA ELITE Xenon light source, CLV-S190 (K111425)	VISERA light source, CLV-S40 (K954451) EVIS universal light source, CLV-U40 (K954451)
Compatible Monitor	OEV-262H (K102379)	OEV-141/201/142/ 202/143/203 (K954451)

Comparator	Subject Device	Predicate Device
Compatible Reprocessor	OER-Pro (K093106)	Not available

Indications for Use

VISERA HYSTEROVIDEOSCOPE OLYMPUS HYF TYPE V 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. Do not use the instrument for any purpose other than its intended use.

Compliance to Voluntary Standards

The following voluntary standards have been applied to the subject device respectively:

- ANSI AAMI ES 60601-1:2005+A1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-2-18:2009 Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
- ANSI AAMI IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3)
- ISO 15739:2017 Photography – Electronic still-picture imaging – Noise measurements
- IEC 62471:2006 Photobiological safety of lamps and lamp systems
- ISO 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
- ISO 10993-12:2012 Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
- ISO 11135:2014 Sterilization of health care products – Ethylene Oxide – requirements for development, validation and routine control of a sterilization process for medical devices
- ISO 10993-7: 2008 Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals [Including: Technical Corrigendum 1 (2009), AMENDMENT 1: Applicability of allowable limits for neonates and infants (2019)]
- ISO 14971:2007 Medical Devices – Application of risk management to medical devices

Device-Specific Guidance

- Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff
- FDA Guidance Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- FDA Guidance Hysteroscopes and Gynecologic Laparoscopes

Summary of Performance Testing

The following performance testing was conducted in support of the substantial equivalence determination.

1. Non-Clinical Bench Testing

Item	Applicable Device	Contents
Thermal Safety	HYF-V	Thermal safety performance test verified compliance to Protection against excessive temperature and other safety hazards of IEC 60601-2-18:2009-08.
Photobiological Safety	HYF-V	The photobiological safety test verified compliance to IEC 32471:2006-07 and confirms the light emitted from subject devices connected to each light source is low enough not to cause injury to the skin and eye.
Noise and Dynamic Range	HYF-V	The substantial equivalence of Noise and Dynamic range between the subject device and predicate device connected with Video System Center / Light Source was confirmed and verified compliant to ISO 15739:2017.
Composite Durability	HYF-V	The durability test against composite stress of mechanical (angulation and wiping during reprocessing) and chemical stress demonstrates the subject device retains its safety and effectiveness against the stresses expected in its use-life.
Color Performance	HYF-V	The color performance of the subject devices is confirmed as substantially equivalent to the predicate devices in the WLI.
Image Intensity Uniformity	HYF-V	The image intensity uniformity of the subject devices is confirmed as substantially equivalent to the predicate devices.
Resolution	HYF-V	The resolution of the subject device is confirmed as substantially equivalent to the predicate device.
Direction of View	HYF-V	The direction of view test verified compliance to ISO 8600-1 and confirms that the subject device is consistent with the design specifications and does not introduce new questions related to safety and effectiveness.
Field of View	HYF-V	The field of view test verified compliance to ISO 8600-1 and confirms that the subject device is consistent with the design specifications and does not introduce new questions related to safety and effectiveness.

2. Animal Test

Animal testing was not applicable and not performed.

3. Biocompatibility Evaluation

Biocompatibility of the subject device was evaluated according to ISO 10993-1 Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing. The subject device passed testing for all applicable biocompatibility endpoints.

4. Sterilization, Shelf Life, Reprocessing

HYF-V and their reusable accessories are not sterilized before shipment. Before using these instruments for the first time and between patient use the endoscopes must be cleaned and high-level disinfected and sterilized as shown in the Instruction for Use. All cleaning, disinfection, and sterilization methods were validated pursuant to FDA Guidance *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff*, issued March 17, 2015. The reprocessing validation was conducted pursuant to the same FDA guidance document. HYF-V is validated as safe and effective for reprocessing with the following:

- Manual Cleaning
- Manual Disinfection with 2 – 3.5% glutaraldehyde
- OER-Pro (K103264)
- Sterilization with EO Gas

5. Electrical Safety and Electromagnetic Compatibility (EMC)

The HYF-V was tested for electrical safety and electromagnetic compatibility inclusive of Essential Performance Requirements in accordance with FDA recognized standards for endoscopic equipment as listed below.

- IEC 60601-1:2005+A1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-2-18:2009 Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
- IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 4)

6. Software Verification and Validation Testing

HYF-V does not include any software; thus, software testing was not applicable and not performed.

7. Risk Analysis

Risk analysis for the subject device was conducted in accordance with established in-house acceptance criteria based on ISO 14971. Design verification tests based on required risk mitigations, and their acceptance criteria were identified and performed as a result of this risk analysis assessment.

These assessments confirmed that there was no unacceptable user-related residual risk for Visera Hysterovideoscope, HYF-V.

8. Clinical Testing

Clinical testing was not applicable and not performed.

Substantial Equivalence Conclusion

HYF-V has the same intended use and has similar technological characteristics as the predicate device. Except for the differences summarized in **Table 5-1**, the technological characteristics, including principle of operation, materials, and directions for use are identical between the subject device and predicate device. The differences in technological characteristics between the subject and predicate do not raise different questions of safety and effectiveness.

The results of non-clinical performance testing demonstrate that the Visera Hysterovideoscope, HYF-V is as safe and effective as the predicate device, and therefore is substantially equivalent to the predicate.