December 29, 2022

Olympus Medical Systems Corp.
℅ Teffany Hutto
Regulatory Affairs Consultant
Olympus Corporation of the Americas
3500 Corporate Parkway, PO Box 610
Center Valley, PA 18034-0610

Re: K221690
Trade/Device Name: OES CYSTONEPHROFIBERSCOPE OLYMPUS CYF-5
OES CYSTONEPHROFIBERSCOPE OLYMPUS CYF-5R
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FAJ
Dated: November 29, 2022
Received: November 29, 2022

Dear Teffany Hutto:

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,

Mark J. Antonino -S

Mark J. Antonino, M.S.
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)*
K221690

Device Name
OES CYSTONEPHROFIBERSCOPE OLYMPUS CYF-5
OES CYSTONEPHROFIBERSCOPE OLYMPUS CYF-5R

Indications for Use *(Describe)*
OES CYSTONEPHROFIBERSCOPEs OLYMPUS CYF-5 and CYF-5R have been designed to be used with an Olympus light source, documentation equipment, display monitor, EndoTherapy accessories and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra and kidney.

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

1. GENERAL INFORMATION

■ 510(k) Submitter: OLYMPUS MEDICAL SYSTEMS CORP.
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■ Contact Person: Teffany Hutto
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■ Manufacturing site: Shirakawa Olympus Co., Ltd.
3-1 Okamiyama, Odakura, Nishigo-mura, Nishishirakawa-gun, Fukushima 961-8061, Japan

Aizu Olympus Co., Ltd.,
3-1-1 Niiderakita, Aizuwakamatsu-shi, Fukushima 965-8520, Japan

2. DEVICE IDENTIFICATION

■ Device Name: OES CYSTONEPHROFIBERSCOPE OLYMPUS CYF-5
OES CYSTONEPHROFIBERSCOPE OLYMPUS CYF-5R

■ Model Name: CYF-5, CYF-5R

■ Common Name: CYSTO-NEPHRO FIBERSCOPE

■ Regulation Number: 876.1500

■ Regulation Name: Endoscope and accessories

■ Regulatory Class: Class II

■ Product Code: FAJ (Cystoscope And Accessories, Flexible/Rigid)

■ Classification Panel: Gastroenterology/Urology

3. PREDICATE DEVICE

■ **Predicate device**

Device name	510(k) Submitter	510(k) No.
VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2, CYF TYPE VA2, CYF TYPE V2R (EVIS EXERA II 180 SYSTEM)	OLYMPUS MEDICAL SYSTEMS CORP.	K133538

4. DEVICE DESCRIPTION

■ **General Description of the subject device**

The subject device has been designed to be used with an Olympus light source, documentation equipment, display monitor, EndoTherapy accessories and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra and kidney.

■ **Principle of Operation**

The subject device consists of three parts: the control section, the insertion section, the eyepiece section. The basic principle including user interface and operation for the procedure of the subject device are identical to that of the predicate device.

■ **List of device components**

The OES CYSTONEPHROFIBERSCOPE OLYMPUS CYF-5 and CYF-5R will be packed and offered together as Table below. They can be used with commercially available Olympus devices as described within the Instruction Manual.

Model No.	Device Name
BW-411B	Single Use Combination Cleaning Brush
MAJ-1413	Light guide adapter
MB-156	ETO cap

5. INDICATIONS FOR USE

OES CYSTONEPHROFIBERSCOPEs OLYMPUS CYF-5 and CYF-5R have been has been designed to be used with an Olympus light source, documentation equipment, display monitor, EndoTherapy accessories and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra and kidney.

6. COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE DEIVCE

The subject device has the same technological characteristics and design as the predicate device except for the following features:

- Optical mechanism
- Optical performance

Validation from non-clinical testing demonstrated that these technological features do not raise any new issues of safety or effectiveness of the subject device.

A side-by-side comparison of the subject device and the predicate device is provided below.

Item	Subject Device	Predicate Device
	OLYMPUS CYF-5, CYF-5R	**OLYMPUS CYF TYPE V2, VA2, V2R (K133538)**
Indications for Use	OES CYSTONEPHROFIBERSCOPEs OLYMPUS CYF-5 and CYF-5R have been been designed to be used with an Olympus light source, documentation equipment, display monitor, EndoTherapy accessories and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra and kidney.	This instrument has been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra, ureter, and kidney.
Regulation Number	21CFR 876.1500	21CFR 876.1500
Regulation Name	Endoscope and accessories	Endoscope and accessories
Regulatory Class	Class II	Class II
Product Code	FAJ	FAJ
Classification Panel	Gastroenterology/Urology	Gastroenterology/Urology
Use Environment	Healthcare facility/hospital	Healthcare facility/hospital
Reprocessing	[Cleaning] AER and manual [Disinfection] AER and manual [Sterilization] - Ethylene oxide gas - STERRAD NX	[Cleaning] AER and manual [Disinfection] AER and manual [Sterilization] - Ethylene oxide gas - STERRAD NX
Single-Use/Reuse	Reusable	Reusable
Duration and type of contact	Surface-contacting device in contact with mucosal membranes. The contact duration is limited exposure (<24 hours).	Surface-contacting device in contact with mucosal membranes. The contact duration is limited exposure (<24 hours).
Depth of Field	3-50mm	3-50mm
Direction of View	0°(Forward viewing)	0°(Forward viewing)
Field of View	120°	120°
Outer Diameter of Distal End	ø 4.6mm (bullet shape)	ø 4.8mm (bullet shape)
Diameter of Insertion Tube	ø 5.5mm	ø 5.4mm

Item	Subject Device	Predicate Device
	OLYMPUS CYF-5, CYF-5R	**OLYMPUS CYF TYPE V2, VA2, V2R (K133538)**
Bending Section Angulation	Up 210° / Down 120°	Up 210° / Down 120°
Working Length	380mm	380mm
Instrument Channel inner diameter	ø 2.4 mm	ø 2.2 mm
Observation mode	WLI	WLI, NBI
Patient contacting material	Insertion tube: Forced dry-hard type of fluorine resin coat Bending section: Fluoro Rubber Glue: Epoxy glue Distal End: Polyphenylsulfone Objective lens/ Light guide lens: Glass Objective lens frame/ Instrument channel pipe/ Instrument channel joint/ Instrument channel port: Stainless Steel Instrument Channel: Polytetrafluoroethylene Rubber seal: Silicone	Insertion tube: Forced dry-hard type of fluorine resin coat Bending section: Fluoro Rubber Glue: Epoxy glue Distal End: Polyphenylsulfone Objective lens/ Light guide lens: Glass Solder: AuSn Solder Instrument channel pipe/ Instrument channel joint/ Junction/ Instrument channel port: Stainless Steel Instrument Channel: Polytetrafluoroethylene Rubber seal: Silicone

7 PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

1) Reprocessing validation testing

Reprocessing instruction and reprocessing method validation testing were conducted and documentations were provided as recommended by Guidance for Industry and Food and Drug Administration Staff, "Reprocessing Medical Devices in Health Care Setting: Validation Methods and Labeling".

2) Biocompatibility testing

Biocompatibility testing were conducted in accordance with the FDA's Guidance for Industry and Food and Drug Administration Staff, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The biocompatibility testing included the following tests:

- Cytotoxicity Study Using the ISO Elution Method
- ISO Intracutaneous Study in Rabbits
- ISO Guinea Pig Maximization Sensitization Test
- ISO Intracutaneous Study in Rabbits
- USP Rabbit Pyrogen Study
- ISO Acute Systemic Toxicity Study in Mice

3) Electrical safety and electromagnetic compatibility (EMC)

Electrical safety testing was conducted in accordance with the ANSI/AAMI ES 60601-1:2005/(R)2012 and A1:2012 and IEC 60601-2-18:2009 standards for safety.

4) Performance testing - Bench

Bench testing as listed below were conducted to ensure that the subject device performs as intended and meet design specifications.

- Thermal Safety
- Composite Durability
- Color performance
- Photobiological Safety
- Image Intensity Uniformity
- Resolution
- Field of View / Direction of View

5) Performance testing - Animal

No animal study was performed to demonstrate substantial equivalence.

6) Performance testing - Clinical

No clinical study was performed to demonstrate substantial equivalence.

7) Risk management

Risk management was performed in accordance with ISO 14971:2007. The design verification tests and their acceptance criteria were identified and performed as a result of this risk management.

8. CONCLUSIONS

Based on the indications for use, technological characteristics, performance testing and technological comparison to the predicate device, the OES CYSTONEPHROFIBERSCOPE OLYMPUS CYF-5 and CYF-5R raise no new issue of safety and effectiveness and are substantially equivalent to the predicate device in terms of safety, effectiveness and performance.