May 21, 2026

Olympus Winter & Ibe GmbH
Daria Schuriner
Regulatory Affairs Manager
Kuehnstr., 61
Hamburg, 22045
GERMANY

Re: K260649
Trade/Device Name: OES ELITE Cystoscope and Accessories; Obturator, 17 Fr. (WA2C17BO); Obturator, 19.8 Fr. (WA2C19BO); Obturator, 21 Fr. (WA2C21BO); Obturator, 21 Fr., for sheath with ramp (WA2C21RO); Obturator, 21 Fr., long (WA2C21LO); Obturator, 21 Fr., for straight sheath (WA2C21SO); Obturator, 22.5 Fr. (WA2C22BO); Obturator, 25 Fr. (WA2C25BO); Obturator, optical, 19.8 Fr. (WA2C19BV); Obturator, optical, 21 Fr. (WA2C21BV); Obturator, optical, 21 Fr., for straight sheath (WA2C21SV); Obturator, optical, 22.5 Fr. (WA2C22BV); Obturator, optical, 25 Fr. (WA2C25BV); Bridge, for 4 mm t elescope (WA2C0NNB); Bridge, one-way, with stopcock (WA2C1BSB); Bridge, one-way (WA2C1BNB); Bridge, two-way, instrument channels from below, with stopcocks (WA2C2BSB); Bridge, two-way, instrument channels from below (WA2C2BNB); Bridge, two-way, instrument channels from above, with stopcocks (WA2C2ASB); Bridge, two-way, instrument channels from above (WA2C2ANB); Cystoscope sheath, 19.8 Fr. (WA2C19BS)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FAJ
Dated: February 27, 2026
Received: February 27, 2026

Dear Daria Schuriner:

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 (the 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 available 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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device

Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 R. Kreitz -S

for 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260649	?

Please provide the device trade name(s). ?

OES ELITE Cystoscope and Accessories;
Obturator, 17 Fr. (WA2C17BO);
Obturator, 19.8 Fr. (WA2C19BO);
Obturator, 21 Fr. (WA2C21BO);
Obturator, 21 Fr., for sheath with ramp (WA2C21RO);
Obturator, 21 Fr., long (WA2C21LO);
Obturator, 21 Fr., for straight sheath (WA2C21SO);
Obturator, 22.5 Fr. (WA2C22BO);
Obturator, 25 Fr. (WA2C25BO);
Obturator, optical, 19.8 Fr. (WA2C19BV);
Obturator, optical, 21 Fr. (WA2C21BV);
Obturator, optical, 21 Fr., for straight sheath (WA2C21SV);
Obturator, optical, 22.5 Fr. (WA2C22BV);
Obturator, optical, 25 Fr. (WA2C25BV);
Bridge, for 4 mm telescope (WA2C0NNB);
Bridge, one-way, with stopcock (WA2C1BSB);
Bridge, one-way (WA2C1BNB);
Bridge, two-way, instrument channels from below, with stopcocks (WA2C2BSB);
Bridge, two-way, instrument channels from below (WA2C2BNB);
Bridge, two-way, instrument channels from above, with stopcocks (WA2C2ASB);
Bridge, two-way, instrument channels from above (WA2C2ANB);
Cystoscope sheath, 19.8 Fr. (WA2C19BS);
Cystoscope sheath, 21 Fr. (WA2C21BS);
Cystoscope sheath, 21 Fr., straight (WA2C21SS);
Cystoscope sheath, 21 Fr., with ramp (WA2C21RS);
Cystoscope sheath, 22.5 Fr. (WA2C22BS);
Cystoscope sheath, 25 Fr. (WA2C25BS);
Cystoscope sheath, 21 Fr., long (WA2C21LS);
Cystoscope sheath, 17 Fr. (WA2C17BS);
Stopcock plug, medium, reusable, 10 pieces (WA1SCM10);
Stopcock plug, large, reusable, 10 pieces (WA1SCL10);
Sealing ring, 5 pieces (WA2CSR05)

Please provide your Indications for Use below. ?

The cystoscopes and accessories are intended for endoscopic diagnosis and therapy in the lower urinary tract. Together with compatible instruments endoscopic diagnostic and therapeutic procedures can be performed. Access is gained through a minimally invasive approach by utilizing natural orifices.

The product is intended to be used for patients from 18 years of age and up.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)	?
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)	?

510(k) Summary

for

OES ELITE Cystoscope and Accessories

I. GENERAL INFORMATION

Manufacturer/ Holder: Olympus Winter and Ibe GmbH
Kuehnstr. 61
22045 Hamburg, Germany
Establishment Registration No.: 9610773

Official Correspondent: Daria Schuriner
Regulatory Affairs Manager
Olympus Winter & Ibe GmbH
Kuehnstr. 61
22045 Hamburg, Germany
Establishment Registration No.: 9610773
Phone: 1-737-349-6843
Daria.Schuriner@olympus.com

Date prepared: April 20, 2026

II. SUBJECT DEVICE

Device trade name: OES ELITE Cystoscope and Accessories

Sheaths:
Cystoscope sheath, 17 Fr. (WA2C17BS);
Cystoscope sheath, 19.8 Fr. (WA2C19BS);
Cystoscope sheath, 21 Fr (WA2C21BS);
Cystoscope sheath, 21 Fr., straight (WA2C21SS);
Cystoscope sheath, 21 Fr., with ramp (WA2C21RS);
Cystoscope sheath, 22.5 Fr. (WA2C22BS);
Cystoscope sheath, 25 Fr. (WA2C25BS);
Cystoscope sheath, 21 Fr., long (WA2C21LS);

Obturators (blind):
Obturator, 17 Fr. (WA2C17BO);
Obturator, 19.8 Fr. (WA2C19BO);
Obturator, 21 Fr. (WA2C21BO);
Obturator, 21 Fr., for sheath with ramp (WA2C21RO);

Obturator, 21 Fr., long (WA2C21LO);
Obturator, 21 Fr., for straight sheath (WA2C21SO);
Obturator, 22.5 Fr. (WA2C22BO);
Obturator, 25 Fr. (WA2C25BO);

Obturators (optical):
Obturator, optical, 19.8 Fr. (WA2C19BV);
Obturator, optical, 21 Fr. (WA2C21BV);
Obturator, optical, 21 Fr., for straight sheath (WA2C21SV);
Obturator, optical, 22.5 Fr. (WA2C22BV);
Obturator, optical, 25 Fr. (WA2C25BV);

Bridges:
Bridge, for 4 mm telescope (WA2C0NNB);
Bridge, one-way, with stopcock (WA2C1BSB);
Bridge, one-way (WA2C1BNB);
Bridge, two-way, instrument channels from below, with stopcocks (WA2C2BSB);
Bridge, two-way, instrument channels from below (WA2C2BNB);
Bridge, two-way, instrument channels from above, with stopcocks (WA2C2ASB);
Bridge, two-way, instrument channels from above (WA2C2ANB);

Stopcock plug, medium, reusable, 10 pieces (WA1SCM10);
Stopcock plug, large, reusable, 10 pieces (WA1SCL10);
Sealing ring, 5 pieces (WA2CSR05).

Common name:	Cystoscopes
Classification name:	Endoscope and Accessories
Regulation number:	21CFR 876.1500
Product code:	FAJ (Cystoscope and Accessories, Flexible/Rigid)
Regulatory class:	II
Submission type:	Traditional 510(k) Submission

III. PREDICATE DEVICE

510k number:	K011496
Product name:	Cysto-Urethroscope 8650 E-line
Applicant:	Richard Wolf GmbH

IV. DEVICE DESCRIPTION

The OES ELITE Cystoscope is an endoscopic, hand-held, rigid, portable, reusable device which is inserted into the patient's bladder through the urethra.

The OES ELITE Cystoscope subject to this submission is comprised of a sheath, blind or optical obturator and a bridge. Device models subject to this submission include 8 sheaths models, 8 compatible blind obturators, 5 compatible optical obturators and 7 bridge models.

The OES Elite Cystoscopes are inserted directly through the natural orifice urethra and are used to visualize a wide range of diagnostic or therapeutic procedures. For therapeutic procedures, the device is used in combination with surgical instruments which can be introduced through the instrument channels.

The OES Elite Cystoscopes and accessories are delivered in non-sterile condition. They are reusable and fully reprocessable. Before first and each subsequent use the device must be inspected and reprocessed according to defined and validated reprocessing methods in the instructions for use.

V. INTENDED USE / INDICATIONS FOR USE

The cystoscopes and accessories are intended for endoscopic diagnosis and therapy in the lower urinary tract. Together with compatible instruments endoscopic diagnostic and therapeutic procedures can be performed. Access is gained through a minimally invasive approach by utilizing natural orifices.

The product is intended to be used for patients from 18 years of age and up.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The indications for use statement for the OES Elite Cystoscope and accessories is very similar to that of the predicate devices. A slightly different wording is chosen and specific description of intended use for each cystoscope part is not provided for the subject device.

The differences do not alter the intended use of the device, nor do they raise different questions of safety and effectiveness of the device relative to the predicate.

The technological characteristics of the subject devices are considered equivalent to the predicate devices.

The subject and predicate devices share the following characteristics:
• general technology (rigid cystoscope),
• general design and dimensions,
• comparable flow rate,
• same reprocessing methods (manual and automated cleaning, steam sterilization).

The following minor differences to the predicate devices exist:
• tip design of several sheath models (additional designs without the beak as well as with beak and ramp),
• one long sheath model (working length 284.5 mm), compared to other sheaths in this submission (working length 212.9 mm)
• design of the bridges with the working channels which allow working instruments insertion from above.

VII. PERFORMANCE DATA

Non-clinical performance testing was conducted in order to demonstrate that the OES ELITE Cystoscope and accessories perform according to their requirements and specifications.

The following tests were performed to verify/validate the design and evaluate the performance:

- Mechanical testing incl. durability testing: compliance with ISO 8600-1 (*9-110*), irrigation flow testing incl. comparative testing to the predicate device, working channel performance, compatibility with endoscopic accessories, tests related to the expected service life.

- Electrical safety testing confirmed compliance with IEC 60601-1:2020 (*19-49*), IEC 60601-2-18 (*9-114*) and IEC 60601-2-2 (*6-389*).

- Biocompatibility testing was conducted in accordance with the ISO 10993 series. All tests indicated biocompatibility of the patient contact materials.

- Reprocessing validation, including:
  - Cleaning validation in accordance with AAMI TIR12:2020 (*14-602*), ANSI AAMI ST98:2022 (*14-583*) and FDA Guidance *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling.*
  - Sterilization validation in accordance with ISO 17664-1:2021 (*14-578*), ANSI/AAMI/ISO 17665-1:2006 (*14-333*) and FDA Guidance

Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling.

- mechanical testing following reprocessing including visual inspection, resistance of the pivotal welding connections of the subject devices as well as tightness of the assembled cystoscope.

- Packaging and transport were verified to be in compliance with ASTM D4169:2022 (*14-576*)

- Human Factors testing was conducted in compliance with the requirements of IEC 62366-1 (*5-129*) and FDA Guidance *Applying Human Factors and Usability Engineering to Medical Devices*. Test participants representing the intended users of the device were included in the human factors validation testing. Observation data and interviews were recorded. Observation of participant performance and the assessment of their understanding of essential information through the interview confirmed that the design of the device is safe and effective for the intended users, uses and user environments.

Risk analysis was carried out in accordance with established internal acceptance criteria based on ISO 14971:2019 (*5-125*).

The results demonstrated that OES ELITE Cystoscope and accessories perform according to their specifications and function as intended.

Clinical data was not used to support substantial equivalence of the subject device to the predicate device.

VIII. CONCLUSIONS

The performance data support the safety of the device and demonstrate that the subject devices comply with the recognized standards as specified and support a substantial equivalence determination.