June 24, 2026

Olympus Medical Systems Corporation
% Eve Smith
Regulatory Affairs Specialist II
Olympus Corporation of the Americas
3500 Corporate Pkwy.
Center Valley, Pennsylvania 18034

Re: K261260
Trade/Device Name: HD Camera Head OLYMPUS CH-S200-08-LB
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FET, NWB
Dated: April 16, 2026
Received: April 16, 2026

Dear Eve Smith:

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: 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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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,

TANISHA L. HITHE -S
Digitally signed by TANISHA L. HITHE -S
Date: 2026.06.24 15:55:03 -04'00'

Tanisha L. Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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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)*
K261260

Device Name
HD Camera Head OLYMPUS CH-S200-08-LB

Indications for Use *(Describe)*
The HD Camera Head OLYMPUS CH-S200-08-LB has been designed to be used with endoscopes, video system center, and other ancillary equipment for endoscopic observation, diagnosis and treatment.

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
K261260

General Information

Applicant: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan 192-8507
Phone: (+81) 42-642-2111
Fax: (+81) 42-642-2307
Establishment Registration Number: 8010047

Applicant Contact: Mr. Shinichiro Kawachi
Correspondent : Olympus Corporation of America
3500 Corporate Parkway
Center Valley, PA 18034

Date Prepared: June 23, 2026

Device Description

Device Name: HD Camera Head OLYMPUS CH-S200-08-LB

Generic/Common Name: HD Camera Head
Regulation Number: 21 CFR 876.1500
Regulatory Class: Class II
Classification Name: Endoscope and accessories
Product Codes: FET, NWB
Review Panel: Gastroenterology/Urology

Predicate Device

Device Name	510(k) Submitter	510(k) No.
Visera Elite II HD 3CMOS Camera Head	Olympus Medical Systems Corporation	K190449

Reference Device

Device Name	510(k) Submitter	510(k) No.
VISERA S VIDEO SYSTEM CENTER OLYMPUS OTV-S500 (OLYMPUS OTV-S500)	Olympus Medical Systems Corporation	K241371

Indications for Use

The HD Camera Head OLYMPUS CH-S200-08-LB has been designed to be used with endoscopes, video system center, and other ancillary equipment for endoscopic observation, diagnosis and treatment.

Device Description

The HD Camera Head OLYMPUS CH-S200-08-LB is part of a visualization system used for endoscopic observation, diagnosis and treatment. The camera head delivers a high definition (HD) image of the targeted area from the endoscope, which is transferred to the monitor for viewing the image of the targeted area. The Charge Coupled Device (CCD) Sensor is located within the camera head and measures the intensity of light and outputs an electrical signal in a proportional relationship with the light image.

The camera head consists of a CCD image sensor, remote switch, focus adjustment mechanism, camera cable and a video connector for connecting with the video system center OTV-S500.

Light is supplied from the video system center OTV-S500 to the endoscope via a light guide cable and emits back from the distal end of the endoscope. The objective lens on the distal end of the endoscope receives the light from the object and the image guide or the relay lens inside the endoscope transfers the light to the eyepiece and CCD sensor, which is inside the subject device. The CCD sensor converts the light to an electrical signal and then the signal is transferred to a video system center via the cable and connector. Finally, an endoscopic image is displayed on the monitor after processing by the video system center.

Comparison of Technological Characteristics

Table 1 compares the subject device to the predicate device with respect to indications for use and technological characteristics, providing detailed information regarding the basis for the determination of substantial equivalence.

Table 1. Subject and Predicate Device Comparison Table

Feature / Characteristic	Subject Device (SD)	Predicate Device (PD)
	HD Camera Head OLYMPUS CH-S200-08-LB	**Visera Elite II HD 3CMOS Camera Head (K190449)**
Indications for Use	The HD Camera Head OLYMPUS CH-S200-08-LB has been designed to be used with endoscopes, video system center, and other ancillary equipment for endoscopic observation, diagnosis and treatment.	The camera head has been designed to be used with Olympus endoscopes, video system center, and other ancillary equipment for endoscopic diagnosis, treatment, and observation.
Regulation No.	21 CFR 876.1500	21 CFR 876.1500
Regulation Name	Endoscope and accessories	Endoscope and accessories
Regulatory Class	Class II	Class II
Product Code	FET, NWB	FET, NWB
Classification Panel	Gastroenterology/Urology	Gastroenterology/Urology
Dimensions – Camera Head	φ32×L 87mm (L-Shape)	W44×H49×L113mm (Straight Shape)
Dimensions – Cable	φ3.4mm×3.5m	φ6.8mm×3m
Head Weight	90g (excluding cable)	220g(excluding cable)
Video Plug	Card edge connector	Card edge connector
Remote Control	Embedded	Embedded
Observation Pickup System	CCD	CMOS
Sterilization	End-user sterilized ETO/ STERRAD/V-PRO	End-user sterilized STERRAD/V-PRO

The HD Camera Head OLYMPUS CH-S200-08-LB is substantially equivalent to the legally marketed predicate device given the similarities in indications for use and technological features with the predicate device:

- similar indications for use
- device characteristics (design and operations) are similar or identical to the predicate device, and
- does not introduce any new or novel treatments or standard of care that differs from predicate device in commercial use.

The Subject Device is smaller, thinner and lighter than the Predicate Device. This is intended for the comfort and convenience of the end user (physician). Additionally, the Subject Device contains a CCD Image Sensor, vs the CMOS Image Sensor found in the Predicate. Olympus conducted NonClinical (Bench) Performance Testing to demonstrate substantial equivalence of the subject device to the predicate device.

Summary of Performance Testing

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

- **Performance Testing – Bench (Non-Clinical)**

The following performance bench tests were conducted to demonstrate substantial equivalence between the subject and predicate devices. All test samples passed pre-defined acceptance criteria.

- Field of View/Direction of View (confirmed to comply with ISO 8600-3 Second edition 2019-08 Endoscopes - Medical endoscopes and endotherapy devices Part 3: Determination of field of view and direction of view of endoscopes with optics)
- Resolution
- Noise and Dynamic Range
- Image Intensity Uniformity
- Color Performance
- Latency
- Distortion
- Depth of Field

- **Animal Study**

Olympus conducted animal testing to verify that the NBI Color Performance of the Subject Device is substantially equivalent to that of the Predicate Device.

In the animal test, an endoscope (connected to the camera head) was inserted transvaginally or transurethrally into a living pig, and evaluation videos were acquired for bladder, ureter and/or cervix. User assessment of the videos confirmed that the Subject and Predicate devices are substantially equivalent with respect to NBI Color Performance.

- **Human Factors Testing**

Human factors validation studies were conducted to evaluate and assess the usability of the HD Camera Head OLYMPUS CH-S200-08-LB and its representative instruction manuals during both operation and reprocessing tasks ensuring it can be used safely and effectively by the intended users in the intended use environment.

Two human factors validation studies were completed to evaluate the CH-S200-08-LB. The first validation study evaluated the usability of the HD Camera Head specifically during operational use. The second validation study evaluated the usability of the reprocessing instructions for use (IFU) for the HD Camera Head. Each study assessed usability with representative physicians and technicians who would use the device to perform tasks in their respective environments either during operation or reprocessing.

The Operation Validation Study yielded the following results:

- Physician participants: The critical task success rate was 95.5%. Across these critical tasks, 1.8% were classified as success with difficulty, 0.0% close calls, and 2.3% use errors.
- RN/technician participants: The success rate was 100%. No instances of success with difficulty, close calls, or use errors were observed for this group.

The Reprocessing Validation study yielded an overall 99.15% success rate, 0.17% success with difficulty rate, 0.0% close call rate, and a 0.68% use error rate.

From the results of both studies, Olympus determined that the HD Camera Head OLYMPUS CH-S200-08-LB is safe for the intended users, uses, and use environments.

Human Factors testing for HD Camera Head OLYMPUS CH-S200-08-LB is confirmed to comply with IEC 62366-1 Edition 1.1 2020-06 Medical devices - Part 1: Application of usability engineering to medical devices.

- **Reprocessing, Sterilization, and Shelf Life**

The HD Camera Head OLYMPUS CH-S200-08-LB is distributed non-sterile to the end user. Before using the instrument for the first time and after each use, the device must be reprocessed according to the instructions in the companion Reprocessing Manual. The HD Camera Head OLYMPUS CH-S200-08-LB is validated as safe and effective for reprocessing as detailed in the Reprocessing Manual with the following:

- Manual Cleaning with Endozime AW
- Delayed Manual Cleaning with Endozime AW
- High Level Disinfection

- Sterilization with:
    - o STERRAD 100S
    - Short Cycle o STERRAD
    - NX Standard Cycle o
    - STERRAD 100NX DUO
    - Cycle o V-PRO maX
    - o V-PRO maX2 o
    - Ethylene Oxide Gas

The HD Camera Head OLYMPUS CH-S200-08-LB has a low likelihood of time-dependent product degradation. Therefore, shelf life testing and data was not applicable for the HD Camera Head OLYMPUS CH-S200-08-LB.

Reprocessing and Sterilization for HD Camera Head OLYMPUS CH-S200-08-LB is confirmed to comply with the following standards as noted below.

- ASTM F3321-19 Standard Guide for Methods of Extraction of Test Soils for the Validation of Cleaning Methods for Reusable Medical Devices
- ASTM F3208-20 Standard Guide for Selecting Test Soils for Validation of Cleaning Methods for Reusable Medical Devices
- ISO 14937 Second Edition 2009-10-15 Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
- ANSI AAMI ST77:2013/(R)2018 Containment devices for reusable medical device sterilization
- ANSI AAMI ST58:2013/(R)2018 Chemical sterilization and high-level disinfection in health care facilities
- ASTM F3293-18 Standard Guide for Application of Test Soils for the Validation of Cleaning Methods for Reusable Medical Devices
- ISO 11135 Second edition 2014-07-15 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices [Including: Amendment 1 (2018)]
- ANSI AAMI ST79:2017 & 2020 Amendments A1, A2, A3, A4 Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- ISO 11737-1 Third edition 2018-01 Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on product [Including Amendment 1 (2021)]
- ISO 17664-1 First edition 2021-07 Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices Part 1: Critical and semi-critical medical devices
- ISO 17664-2 First edition 2021-02 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Non-critical medical devices.

- ANSI AAMI ST98:2022 Cleaning validation of health care products - Requirements for development and validation of a cleaning process for medical devices
- ISO 22421 First edition 2022-08 ISO 22421 First edition 2022-08 Sterilization of health care products — Low temperature vaporized hydrogen peroxide — Requirements for the development, validation and routine control of a sterilization process for medical devices
- AAMI TIR12:20 Designing testing and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers

- **Software and Cybersecurity**

Software verification and validation testing of the HD Camera Head OLYMPUS CH-S20008-LB has been performed and documented in compliance with the FDA guidance "Guidance for the Content of Premarket Submissions for Device Software Functions" and "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions." An Enhanced level of software documentation is provided for the subject device.

Software and Cybersecurity for HD Camera Head OLYMPUS CH-S200-08-LB is confirmed to comply with the following standards as noted below.

- INCITS ISO IEC 30111 First edition 2013-11-01 (R2019) Information technology - Security techniques - Vulnerability handling processes
- IEC 62304 Edition 1.1 2015-06 Medical device software - Software life cycle processes
- FIRST CVSS v3.0 Common Vulnerability Scoring System version 3.0
- IEC 81001-5-1 Edition 1.0 2021-12 Health software and health IT systems safety, effectiveness and security - Part 5-1: Security - Activities in the product life cycle
- ANSI NEMA HN 1-2019 American National Standard Manufacturer Disclosure Statement for Medical Device Security

- **Electrical Safety and Electromagnetic Compatibility**

Electrical safety and EMC performance testing for HD Camera Head OLYMPUS CH-S20008-LB is confirmed to comply with the following standards as noted below.

- ANSI AAMI ES 60601-1:2005+A1:2012+A2:2021 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014+A1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests (Edition 4.1)
- IEC 60601-2-18: Edition 3.0 2009-08 Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment

- IEC 60601-1-6 Edition 3.2 2020-07 Medical electrical equipment - Part 1-6: General Requirements for basic safety and essential performance – Collateral standard: Usability
- IEC 62471 First Edition 2006-07 Photobiological Safety of lamps and lamp systems
- IEC TR 60601-4-2 Edition 1.0 2016-05 Medical electrical equipment - Part 4-2: Guiance and Interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

Conclusion

In summary, HD Camera Head OLYMPUS CH-S200-08-LB is substantially equivalent to the predicate device.

Predetermined Change Control Plan

A Predetermined Change Control Plan (PCCP) is accompanying Olympus' 510(k) for the Subject Device. This plan proposes the compatibility of the HD Camera Head OLYMPUS CH-S200-08-LB with the Video System Center OTV-S700 (in addition to the Video System Center presented in the context of the 510(k), OTV-S500). The compatibility with the OTV-S700 (K251336) is intended to increase the device's usefulness in the clinical setting.

The modification requires no software or hardware changes. No additional modifications are proposed. No physical changes will be applied to the device itself.

The validation activities and performance requirements aim to confirm the compatibility of the camera head with the OTV-S700 and are as follows:

- **Non-Clinical Bench Testing (PCCP)**

  Olympus will perform Verification tests utilizing the video system center OTV-S700 to demonstrate compatibility of the camera head with the system.

  Comparison testing (CH-S200-08-LB connected to the OTV-S700 vs. CH-S200-08-LB connected to the OTV-S500) will be performed to demonstrate the similarity between the two.

- **Software and Cybersecurity Testing (PCCP)**

  No changes are planned to the software/software function of the CH-S200-08-LB as result of this Predetermined Change Control Plan. Software Requirement Specifications (SRS) will be updated for the combination with the OTV-S700, and Software Testing as part of Verification and Validation (with OTV-S700) will be performed.

  Cybersecurity will be evaluated where the outcome is reliant upon the subject device being connected to the OTV-S700 video system.

- **Electrical Safety/EMC (PCCP)**

  The EMC considerations of the device will remain the same as in the 510(k). The level of harm will stay as “Non-Serious Adverse Events” and the Electrical Safety and EMC testing will be performed as they were for compatibility with the OTV-S500 Video System Center.

- **Animal Study (PCCP)**

  Olympus will conduct animal testing to verify that the NBI Color Performance of the Subject Device when connected to the video system center OTV-S700 is comparable to that of the Subject Device when connected to the video system center OTV-S500.

The CH-200-08-LB Operations Manual will be updated to add OTV-S700 as a compatible video system center. The changes will be made to the Appendix section, where the equipment compatible with the camera head is described.

Olympus will notify users of this update as follows:

- Existing Customers: The CH-200-08-LB Operations Manual on Olympus’ website will be updated and accessible to users. Olympus sales representatives will provide customers with the updated IFU as needed.
- New customers: The updated CH-S200-08-LB Operations Manual will be provided to customers with the Subject Device.