August 11, 2025

Univlabs Technologies Private Limited
Vishwanath Pratap Singh
Engineering Director
Plot No : 31, Sector -33, Near Info-City 2
Haryana
Gurugram, HR 122003
India

Re: K250462
Trade/Device Name: UL UHD-Clear View 4K Camera System (UL-3Chip 4K)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FET
Dated: June 27, 2025
Received: July 7, 2025

Dear Vishwanath Pratap Singh:

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.

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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: 2025.08.11 20:45:14 -04'00'

Tanisha Hithe, M.S., M.HS.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control 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.	K250462

Please provide the device trade name(s).

UL UHD-Clear View 4K Camera System (UL-3Chip 4K)

Please provide your Indications for Use below.

The UL UHD-Clear View 4K Camera System (UL-3Chip 4K), consisting of a Camera Control Unit and an Endoscopic Camera Head, is indicated for use with compatible endoscopes to provide visualization during general endoscopic procedures. These procedures may involve the visual inspection of internal anatomical structures to support diagnostic or therapeutic interventions. Patient suitability for particular endoscopic procedures must be determined by the responsible physician based on the individual's clinical condition.

Please select the types of uses (select one or both, as applicable).

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

510(k) #: K250462

510(k) Summary

Prepared on: 2025-07-04

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	UnivLabs Technologies Private Limited
Applicant Address	Plot No : 31, Sector -33, Near Info-City II Haryana Gurugram HR 122003 India
Applicant Contact Telephone	+91-9560925518
Applicant Contact	Mr. SUNIL KUMAR SINGH
Applicant Contact Email	sunil@univlabs.in
Correspondent Name	UnivLabs Technologies Private Limited
Correspondent Address	Plot No : 31, Sector - 33, Near Info-City II Haryana Gurugram HR 122003 India
Correspondent Contact Telephone	+91-9491729764
Correspondent Contact	Mr. Venkataramana Anant Bhagavati
Correspondent Contact Email	regulatory@univlabs.in

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	UL UHD-Clear View 4K Camera System (UL-3Chip 4K)
Common Name	Endoscope and accessories
Classification Name	Endoscopic Video Imaging System/Component, Gastroenterology-Urology
Regulation Number	876.1500
Product Code(s)	FET

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K201135	Image1 S CCU (TC200US, TC201US, TC300US, TC301US, TC302US, TC304US); Image1 S 4U Camera Head (TH120)	FET

Device Description Summary

21 CFR 807.92(a)(4)

The UL UHD-Clear View 4K Camera System (UL-3Chip-4K) consisting of a Camera Control Unit (CCU) and Endoscopic Camera Head supports video output up to 4K resolution for connection to external medical-grade display monitors. The Camera Control Unit (CCU) processes electronic signals transmitted from an endoscopic camera head and outputs the video signal to an external display monitor.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The UL UHD-Clear View 4K Camera System (UL-3Chip 4K), consisting of a Camera Control Unit and an Endoscopic Camera Head, is indicated for use with compatible endoscopes to provide visualization during general endoscopic procedures. These procedures may involve the visual inspection of internal anatomical structures to support diagnostic or therapeutic interventions. Patient suitability for particular endoscopic procedures must be determined by the responsible physician based on the individual's clinical condition.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The subject device, UL UHD-Clear View 4K Camera System, is indicated for use with compatible endoscopes to provide visualization during general endoscopic procedures. The predicate device, Karl Storz Image 1S CCU and 4U Camera Head, is indicated for visualization, image recording, and documentation during endoscopic and microscopic procedures. The subject device does not support image recording or documentation. These are minor differences, and the subject device's indications represent a subset of the predicate's. Additional labeling language in the subject device (e.g., references to physician judgment and support for diagnostic or therapeutic interventions) is intended to provide clarity and is consistent with the IMDRF definition of "Indications for Use." It does not broaden the scope of intended use. Therefore, the indications for use of the subject device do not constitute a new indication for use.

Technological Comparison 21 CFR 807.92(a)(6)

The UL UHD-Clear View 4K Camera System (UL-3Chip-4K) consisting of a Camera Control Unit (CCU) and Endoscopic Camera Head supports video output up to 4K resolution for connection to external medical-grade display monitors. The Camera Control Unit (CCU) processes electronic signals transmitted from an endoscopic camera head and outputs the video signal to an external display monitor.

Both the subject and predicate device are based on CMOS Sensor technology with a sensor resolution of 3840*2160p. Both Subject and predicate device(s) have adaptive zoom and 12G/3G-SDI display port(s). Additionally, the subject device has additional two HDMI port(s).

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Comparative Bench Testing was performed between the subject device and predicate device for the following parameters in order to ensure Proper Characterization of Image Quality :

- Spatial Resolution
- Depth of Field
- Field of View
- Zoom Characterization
- Color Enhancement

There are no performance standards or special controls developed for Camera Control Unit (CCU) and Endoscopic Camera Head(s). However, UL UHD-Clear View 4K Camera System (UL-3Chip 4K) is tested according to following FDA recognized consensus standards :

- IEC 60601-1 : 2005 + AMD1 : 2012 + AMD2 : 2020 : Medical Electrical Equipment - Part 1 : General Requirements for Basic Safety and Essential Performance.
- IEC 60601-1-2 : 2014 + AMD1 : 2020 : Medical Electrical Equipment - Part 1- 2 : Collateral Standard : Electromagnetic Disturbances - Requirements and Tests.

The essential performance for the above tests confirms to IEC 60601-2-18 : 2009 : Particular requirements for the basic safety and essential performance of endoscopic equipment.

Software Verification & Validation Testing was performed as per Content of Premarket Submissions for Device Software Functions (Moderate Level of Concern).

"Not Applicable"

The subject and predicate device have similar indications for use and technological characteristics as the predicate device. The minor differences between the subject and predicate devices do not raise different questions of safety and effectiveness. Non-clinical performance testing (Bench Testing), electromagnetic compatibility (EMC), electrical, mechanical, and thermal safety, demonstrates that the subject device is as safe and effective as the predicate. Therefore, the UL UHD-Clear View 4K Camera System (UL-3Chip 4K) is substantially equivalent to the predicate device.