March 6, 2026

Calyxo, Inc.
Nitya Narayanan
Director, Regulatory Affairs
4473 Willow Rd.
Suite 100
Pleasanton, California 94588

Re: K260013
Trade/Device Name: CVAC Image Processor
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FGB
Dated: January 2, 2026
Received: January 5, 2026

Dear Nitya Narayanan:

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, 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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260013

Device Name
CVAC Image Processor

Indications for Use *(Describe)*
The CVAC Image Processor is only to be used with the CVAC Aspiration System to provide treatment and removal of urinary stones (kidney stones, fragments, and dust) and endoscopic examination of the urinary tract and the interior of the 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

1. GENERAL INFORMATION

1.1 Submitter and 510(k) Owner

Calyxo, Inc.
4473 Willow Road, Suite 100
Pleasanton, CA 94588

1.2 Official Correspondent

Ms. Nitya Narayanan
4473 Willow Road, Suite 100
Pleasanton CA 94588
Telephone: (408) 802-8146
Email: nitya.narayanan@calyxoinc.com

1.3 Date of Preparation

January 2, 2026

2. NAME OF THE DEVICE

2.1.1 Trade/Proprietary Name

CVAC® Image Processor

2.1.2 Common/Usual Name

Ureteroscope and Accessories, Flexible/Rigid

2.1.3 Classification Information

Trade/Proprietary Name:	CVAC® Image Processor
Common/Usual Name:	Ureteroscope and Accessories, Flexible/Rigid
Classification Name:	Endoscope and Accessories
Classification Regulation:	21 CFR 876.1500
Class:	II
Product Codes:	FGB, Ureteroscope and Accessories, Flexible/Rigid
Panel:	Gastroenterology / Urology

3. PREDICATE DEVICE

The predicate device is the CVAC Image Processor, which is part of the CVAC Set cleared under K233472.

4. DESCRIPTION OF THE DEVICE

The single use CVAC Aspiration System and the reusable CVAC Image Processor are designed to work together. The devices allow physicians to locate kidney stones and to establish a conduit

during endoscopic urological procedures for the treatment and removal of urinary stones (kidney stones, fragments, and dust). The devices are used in a surgical suite and are compatible with standard hospital monitors, vacuum sources, and irrigation sources.

There are no changes to the CVAC Aspiration System in this 510(k), including the camera assembly, optical wiring, or LED assembly.

The CVAC Image Processor, the subject device, is a software-controlled, reusable and electrical image processor. The CVAC Image Processor is connected to a standard 110V hospital electrical outlet via a provided power cord. The internal carrier board inside the CVAC Image Processor houses the LED control circuit, the display interface, and supports electrical interconnect between the image signal processing module and the System-on-Module (SOM). This allows the CVAC Image Processor to generate a video signal compatible with standard hospital grade external monitors. Accessories provided with the CVAC Image Processor include a HDMI-to-DVI adapter, a HDMI cable, and a power cable. The CVAC Image Processor software is updated to v1.5 in this submission.

5. INTENDED USE

The intended use / indications for use for the CVAC Aspiration System and CVAC Image Processor is as follows:

> The CVAC Image Processor is only to be used with the CVAC Aspiration System to provide treatment and removal of urinary stones (kidney stones, fragments, and dust) and endoscopic examination of the urinary tract and the interior of the kidney.

6. INTENDED USE COMPARED TO THE PREDICATE

The intended use and indications for use statement is unchanged from the predicate device cleared under K233472.

7. TECHNOLOGY CHARACTERISTICS COMPARED TO THE PREDICATE

There are minor modifications to the software and small hardware changes to the CVAC Image Processor made under design controls. The software was updated to SW v1.5. This resulted in a full suite of software testing and cybersecurity upgrades to confirm that bench and software performance meets requirements and specifications.

The different technological characteristics between the subject device and the predicates have been evaluated and was demonstrated not to raise new questions of safety and effectiveness.

Table 1. Technology Comparison of Subject and Predicate Devices

	Subject Device CVAC Image Processor in the CVAC Set	**Predicate Device CVAC Image Processor cleared in the CVAC Set K233472**
Image System	The CVAC Image Processor is connected to the CVAC Aspiration System and provides power to the ureteroscope	The CVAC Image Processor is connected to the CVAC Aspiration System and provides power to the ureteroscope
Compatible Display	Standard Monitor with HDMI or DVI input	Standard Monitor with HDMI or DVI input
OPTICAL TEST PARAMETERS		
Resolution (pixels)	200 x 200	200 x 200
Digital Video Technology	Color CMOS	Color CMOS
Illumination	LED	LED
Field of View (°)	120°	120°
Direction of View (°)	0°	0°
Light (lux)	~5500 lux at 6 mm	~5500 lux at 6 mm
UPDATED SOFTWARE FEATURES		
Software Architecture Modifications	Improved system performance [*Software testing*]	System was stable and passed all testing
Cybersecurity Updates	Update cybersecurity [*Cybersecurity testing*]	Cybersecurity testing passed
Image processing optimization	Improved noise reduction, enhanced brightness uniformity, optimized memory management [*Image Processor Optical testing*]	Optical testing passed
System reliability	Added comprehensive error handling, logging frameworks, failover mechanisms to reduce the potential for system crashes and improve diagnostic capabilities [*Reliability testing*]	System reliability testing passed
Minor hardware modifications	Continuous improvement to update the logo on the case and to improve electromechanical robustness [*Design Controls*]	Complied with standards of the day

8. PERFORMANCE TESTING

The 510(k) submission provides performance data to establish the substantial equivalence of the CVAC Image Processor (the subject device) to the predicate device CVAC Image Processor (K233472). A summary of these performance tests is provided below.

Software and Cybersecurity Testing: Software verification and validation testing were conducted, and documentation was provided as recommended by FDA guidance documents, "Content of Premarket Submissions for Device Software Functions," issued on June 14, 2023, and "Off-The-Shelf Software Use in Medical Devices," issued on August 11, 2023. Cybersecurity risk assessment was updated in accordance with FDA guidance document, "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions," issued on September 27, 2023. The software complies with IEC 62304.

Optical Testing**:** Optical testing was successfully performed to appliable requirements of ISO 62471, ISO 8600-1, ISO 8600-3, ISO 8600-4 and ISO 8600-6. Some parameters were marginally different, consistent with the updates made to the Image Signal Pipeline (ISP). No differences were found that would negatively impact visualization in the CVAC Set's clinical application.

System Verification and Validation*:* Verification and validation activities demonstrated that all customer requirements passed validation and all impacted product requirements passed verification.

Performance Test, in vivo model: A design validation study was conducted using an in vivo porcine kidney model to confirm that the optical properties of the CVAC Set meets product specifications, and that the device meets design input requirements.

Leveraged Data: The following data were leveraged from the predicate device submission as the device modifications were demonstrated not to impact the results of this testing:

- Electrical Safety and Electromagnetic Compatibility
- Cleaning and Disinfection Validation
- Packaging and Useful Life

9. CONCLUSIONS

Results of the substantial equivalence analysis led to the conclusion that the CVAC Image Processor with SW v1.5 is substantially equivalent to the CVAC Image Processor cleared under K233472.