April 13, 2026

Calyxo, Inc.
Nitya Narayanan
Director, Regulatory Affairs
4473 Willow Road, Suite 100
Pleasanton, CA 94588

Re: K260965
Trade/Device Name: CVAC Aspiration System
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FED, FGB
Dated: March 23, 2026
Received: March 23, 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, 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

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)*
K260965

Device Name
CVAC Aspiration System

Indications for Use *(Describe)*
The CVAC Aspiration System and CVAC Image Processor consists of a sterile single use, steerable ureteral catheter and a reusable software-controlled image processor. It is intended to establish a conduit during endoscopic urological procedures for the treatment and removal of urinary stones (kidney stones, fragments, and dust). It employs flexible ureteroscopy within the urinary tract for endoscopic examination of the urinary tract and the interior of the kidney.

The steerable ureteral catheter is used for irrigation and aspiration of kidney stones and stone dust with dedicated irrigation and vacuum channels under ureteroscopy. The CVAC Aspiration System + CVAC Image Processor can be used with additional accessories to perform various diagnostic and therapeutic procedures.

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

March 20, 2026

2. NAME OF THE DEVICE

2.1.1 Trade/Proprietary Name

CVAC Aspiration System

2.1.2 Common/Usual Name

Endoscopic Access Overtube, Gastroenterology-Urology

Ureteroscope and Accessories, Flexible/Rigid

2.1.3 Classification Information

Classification Name:	Endoscope and Accessories
Classification Regulation:	21 CFR 876.1500
Class:	II
Product Codes:	FED, Endoscopic Access Overtube, Gastroenterology-Urology FGB, Ureteroscope and Accessories, Flexible/Rigid
Panel:	Gastroenterology / Urology

3. PREDICATE DEVICE

The predicate device is the CVAC Aspiration System, 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. There is no change to the CVAC Image Processor. This submission finalizes labeling changes for the devices.

5. INTENDED USE

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

> The CVAC Aspiration System and CVAC Image Processor consists of a sterile single use, steerable ureteral catheter and a reusable software-controlled image processor. It is intended to establish a conduit during endoscopic urological procedures for the treatment and removal of urinary stones (kidney stones, fragments, and dust). It employs flexible ureteroscopy within the urinary tract for endoscopic examination of the urinary tract and the interior of the kidney.
>
> The steerable ureteral catheter is used for irrigation and aspiration of kidney stones and stone dust with dedicated irrigation and vacuum channels under ureteroscopy. The CVAC Aspiration System and CVAC Image Processor can be used with additional accessories to perform various diagnostic and therapeutic procedures.

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

The technology of the CVAC Aspiration System subject and predicate devices are the same. This 510(k) is intended for labeling changes only. The Instructions for Use (IFU) for the CVAC Aspiration System are revised to incorporate previously communicated recall-related updates, improve clarity and readability, and enhance consistency across sections. Changes include minor editorial updates, reorganization and clarification of existing warnings, cautions, and operating instructions, and expanded troubleshooting guidance related to fluid outflow and device handling. These revisions do not change the device intended use, indications for use, design, materials, performance specifications, or fundamental operating principles, and do not introduce new risks or raise new questions of safety or effectiveness.

8. DESIGN CONTROL ACTIVITIES

Risk management updates, design review, design verification and validation, and instructions for use changes were all performed under design controls and according to design and development requirements.

9. CONCLUSIONS

Results of the substantial equivalence analysis led to the conclusion that the CVAC Aspiration System is substantially equivalent to the CVAC Aspiration System cleared under K233472.