February 2, 2024

Calyxo, Inc.
Diane Mandell Horwitz, Ph.D.
Regulatory Consultant
4473 Willow Road, Suite 100
Pleasanton, CA 94588

Re: K233472
Trade/Device Name: CVAC Aspiration System and CVAC Image Processor
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FED, FGB
Dated: January 4, 2024
Received: January 4, 2024

Dear Diane Mandell Horwitz:

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.

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)*
K233472

Device Name
CVAC Aspiration System and CVAC Image Processor

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 and 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.

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510(k) SUMMARY

1. GENERAL INFORMATION

1.1 Submitter and 510(k) Owner

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

1.2 Official Correspondent

Diane Horwitz, Ph.D.
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1.3 Date of Preparation

January 11, 2024

2. NAME OF THE DEVICE

2.1.1 Trade/Proprietary Name

CVAC Aspiration System and CVAC Image Processor

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 Code:	FED, Endoscopic Access Overtube, Gastroenterology-Urology FGB, Ureteroscope and Accessories, Flexible/Rigid
Panel:	Urology

3. PREDICATE DEVICES

The primary predicate device is the CVAC Aspiration System (formerly K-VAC Aspiration Catheter, Calyxo, Inc, K200149). The secondary predicate is Axis Single-Use Digital Flexible Ureteroscope (K180367, Shanghai AnQing Medical Instrument CO., Ltd.).

4. DESCRIPTION OF THE DEVICE

The single use CVAC Aspiration System and the reusable CVAC Image Processor are specialized devices designed to 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.

The CVAC Aspiration System is a sterile single-use steerable ureteral catheter employing ureteroscopy with built-in irrigation and vacuum functionality. Accessories provided with the CVAC Aspiration System include an introducer, a laser bridge, a trigger tie, a 3-way stopcock, and a vacuum port cap. The CVAC Aspiration System catheter is compatible with commercially available accessories for stone removal such as appropriately sized single-use laser fibers and stone baskets, which are inserted and used in the vacuum channel. The CVAC Aspiration System connects to the CVAC Image Processor via an attached video cable.

The CVAC Image Processor 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.

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 of the CVAC Aspiration System and CVAC Image Processor includes the combined intended uses of both predicate devices. The mode of operation is the same as the combined modes of action of both predicate devices but is based on the mode of action of the primary predicate. Placement procedures for the subject device and primary predicate are the same. The subject device provides visualization during the procedure, similar to the secondary predicate. The combination of the two capabilities provides a streamlined ability to remove kidney stones and stone dust.

7. TECHNOLOGY CHARACTERISTICS COMPARED TO THE PREDICATE

There are similarities between the technological characteristics of CVAC Aspiration System and CVAC Image Processor and the primary predicate, and between the subject devices and the secondary predicate. Similarities to the primary predicate include the mode of use of the device, the working length, OD, ID, external catheter profile, the dedicated irrigation channel and aspiration channel and the functionality for irrigation and aspiration of small kidney stones and stone dust.

Differences compared to the primary predicate include the built-in digital imaging in the subject device, the software controls and electronics, while the primary predicate relies on fluoroscopy for visualization. Additionally, the subject device has a hydrophilic coating to aid in placement.

The CVAC Aspiration System and CVAC Image Processor and the secondary predicate are similar in that both devices are flexible single-use sterile ureteroscopes designed to be used with one companion image processor. Both have visualization via a camera chip at the catheter tip, both are software-controlled and electronic. Table 1 below reviews the technological comparison between the subject device and both predicates.

The different technological characteristics between the subject device and the predicates have been evaluated and it has been determined the subject device does not raise new questions of safety and effectiveness. The sum of the technology of the primary predicate and the secondary predicate supports the substantial equivalence determination.

Table 1. Technology Comparison of CVAC Aspiration System and CVAC Image Processor and Predicate Devices

	Subject Device CVAC Aspiration System and CVAC Image Processor	**Primary Predicate** CVAC Aspiration System **K200419**	**Secondary Predicate** Axis Disposable Ureteroscope **K180367**
Working Length	70 cm	70 cm	65 cm
Total Length	100 cm	90 cm	92 cm
Shaft OD	<12 Fr (4 mm)	<12 Fr (4 mm)	9.3 Fr (3.1 mm)
Working Channel ID (also referred to as Vacuum Channel)	7 Fr (2.3 mm)	7.5 Fr (2.5 mm)	3.6 Fr (1.2 mm)
External Catheter Profile	Diameter and length sufficient to reach kidney, low durometer PEBAX outer material at tip, smooth outer surface	Diameter and length sufficient to reach kidney, low durometer PEBAX outer material at tip, smooth outer surface	Diameter and length sufficient to reach kidney
Navigation	Ureteroscopic navigation.	Initial placement and navigation are done under fluoroscopy.	Ureteroscopic navigation.
Coating	Hydrophilic Coating on distal ≈45 cm of the catheter	No coating	No coating
Distal Tip Configuration (Camera)	Recessed CMOS chip and dual LEDs for direct vision capability	N/A	Recessed CMOS chip and dual LEDs for direct vision capability
Single or multiple use	Single patient use	Single patient use	Single patient use

Table 1. Technology Comparison of CVAC Aspiration System and CVAC Image Processor and Predicate Devices

	Subject Device CVAC Aspiration System and CVAC Image Processor	**Primary Predicate** CVAC Aspiration System **K200419**	**Secondary Predicate** Axis Disposable Ureteroscope **K180367**
IRRIGATION / ASPIRATION			
Irrigation	Via the irrigation port and irrigation channel at catheter tip. Irrigation channel is separate and distinct from working channel.	Via the irrigation port and irrigation channel at catheter tip. Irrigation channel is separate and distinct from working channel.	Via access port through the working channel
Aspiration	Use hospital vacuum, setting of 150 to 200 mmHg	Use hospital vacuum, setting of 150 to 200 mmHg	No vacuum capabilities
Stone Collector	Integrated into handle	In-line stone collector separate from device	No stone collector
ACCESSORIES AND COMPATIBILITY WITH OTHER DEVICES			
Compatible medical devices	Compatible with standard guidewires and 200-series laser fibers. Compatible with standard stone baskets size 1.9Fr	Compatible with standard guidewires.	"Additional accessories" may be used per Axis IFU. This includes laser fibers that fit inside the working channel (including 200-series laser fibers). Compatible with stone baskets.
Introducer Provided?	Yes (provided in sterile tray)	Yes (provided in sterile tray)	No
Compatible Ureteral Access Sheath sizes	If clinician desires, can be used with 12/14 Fr ureteral sheath	If clinician desires, can be used with 12/14 Fr ureteral sheath	If clinician desires, can be used with 11/13 Fr or 12/14 Fr ureteral sheath
IMAGE PROCESSOR			
Image System	The CVAC Image Processor is connected to the CVAC Aspiration System and provides power to the ureteroscope	None	The Video Processor is connected to the flexible ureteroscope and provides power to the ureteroscope
Compatible Display	Hospital-grade High-Definition Monitor with HDMI or DVI input	N/A	Hospital-grade High-Definition Monitor with HDMI or DVI input
Resolution (pixels)	200 x 200	N/A	400 x 400
Digital Video Technology	Color CMOS	N/A	Color CMOS
Illumination	LED	N/A	LED
Field of View (º)	100º	N/A	110º
Direction of View (º)	0°	N/A	0°
Light (lux)	6000 lux	N/A	>5000 lux

8. PERFORMANCE TESTING

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

Performance Test, Bench: Results of extensive bench performance verification and validation testing confirm that the aspiration and irrigation and other device characteristics meet product specifications, and the device meets design input requirements.

Usability Assessment: A usability assessment was conducted to evaluate the User's understanding of the User Manuals and Quick Reference Guide when performing and asked about critical tasks during use of the CVAC Aspiration System and CVAC Image Processor. Results confirm that the acceptance criteria for usability have been met by intended users in the intended use environments. All participants were observed to safely perform all primary operating functions and critical tasks. The risk profile was acceptable, user training and User Manuals and Quick Reference Guide were interpreted correctly.

Biocompatibility Data: Biocompatibility testing was conducted for the CVAC Aspiration System and accessories as an external communicating device, tissue/bone/dentin contacting, limited duration exposure. Cytotoxicity (MEM Elution Method), Sensitization (Guinea Pig Maximization Test, Magnusson-Kligman Method), Irritation (Intracutaneous test), Acute Systemic Toxicity, Material Mediated Pyrogen Test (LAL Test) testing all resulted in passing test results. This conclusion is that the CVAC Aspiration is biocompatible and meets the requirements of ISO 10993-1.

Electrical Safety and Electromagnetic Compatibility: Electrical safety and electromagnetic compatibility (EMC) was successfully performed to applicable requirements of IEC 60601-1, IEC 60601-1-2, and IEC 60601-4-2.

Optical Testing**:** Optical testing was successfully performed to appliable requirements of ISO 8600-1, ISO 8600-3, ISO 8600-4 and ISO 8600-6.

Software: 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 conducted 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.

Sterilization: Sterilization validation studies using ethylene oxide (EtO) confirmed sterilization to a sterility assurance level (SAL) of 10^{-6}. The sterilization process was validated in accordance with ANSI AAMI ISO 11135: 2014, Over-Kill Approach.

Packaging and Shelf Life: Packaging validation testing, including transportation and distribution testing, demonstrated the product packaging protects and maintains device integrity and functionality for the CVAC Aspiration System and CVAC Image Processor. It also confirmed that the product packaging maintained product sterility and supports a 12-month shelf life for the CVAC Aspiration System.

9. CONCLUSIONS

This 510(k) submission demonstrates that the CVAC Aspiration System and CVAC Image Processor is substantially equivalent to the predicate devices.