May 22, 2020

Kalera Medical, Inc.
% Diane Horwitz, Ph.D., RAC
Regulatory Consultant
Mandell Horwitz Consultants, LLC
5 Lake Como Ct.
Greenville, SC 29609

Re: K200419
Trade/Device Name: Kalera Vacuum Aspiration Catheter™ (K-VAC™)
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FED
Dated: April 27, 2020
Received: April 28, 2020

Dear Diane 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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Martha W. Betz, Ph.D.
Acting 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*

K200419

Device Name
Kalera Vacuum Aspiration Catheter™ (K-VAC™)

Indications for Use *(Describe)*
The Kalera Vacuum Aspiration Catheter (K-VAC™) is used to establish a conduit during endoscopic urological procedures for the treatment of urinary stones.

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

Kalera Medical, Inc.
4473 Willow Road, Suite 100
Pleasanton, CA 94588

### 1.2 Official Correspondent

Diane Horwitz, Ph.D.
Regulatory Consultant
5 Lake Como Ct.
Greenville, SC 29609
Telephone: 703.307.2921
Email: dmh@mandellhorwitzconsulting.com

### 1.3 Date of Preparation

May 21, 2020

## 2. NAME OF THE DEVICE

### 2.1.1 Trade/Proprietary Name

Kalera Vacuum Aspiration Catheter™ (K-VAC™)

### 2.1.2 Common/Usual Name

Endoscopic Access Overtube, Gastroenterology-Urology

### 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 |
| Panel: | Gastroenterology / Urology |

## 3. PREDICATE DEVICE

The predicate device is ClearPetra Suction-Evacuation Sheath (Well Lead Medical Co., Ltd., K161110).

## 4. DESCRIPTION OF THE DEVICE

K-VAC is a sterile, single-use aspiration-irrigation catheter that is designed to assist in the removal of stone fragments during standard ureteroscopy. K-VAC is a dual-lumen catheter with two concentric lumens. The outer lumen is the irrigation lumen that accommodates delivery of irrigation/contrast solution. The larger, inner lumen is the aspiration lumen through which the stone fragments are removed. The inner diameter of the aspiration lumen is 2.5 mm. The distal 5 cm of the K-VAC tip is soft with a steering mechanism on the catheter handle and embedded wires to actuate the tip. In this way, stones and debris in the renal calyces can be fluidized with irrigation and aspirated.

An additional component to the device is a radiopaque introducer, which is 0.035" and 0.038" guidewire compatible. The tip of the introducer has a soft tapered tip.

The design of K-VAC allows the trained operator to maneuver and position K-VAC via a standard 12/14F ureteral access sheath under fluoroscopic guidance, followed by controlled irrigation and aspiration of stones and debris from the renal pelvis and calyces.

K-VAC is composed of well-characterized biocompatible materials commonly used in urinary catheters. The catheter is mechanical and contains no electrical components.

## 5. INTENDED USE

The intended use / indications for use for the Kalera Vacuum Aspiration Catheter (K-VAC) as follows:

> The Kalera Vacuum Aspiration Catheter™ (K-VAC™) is used to establish a conduit during endoscopic urological procedures for the treatment of urinary stones.

## 6. INTENDED USE COMPARED TO THE PREDICATE

The intended use of the Kalera Vacuum Aspiration Catheter (K-VAC) is the same as the predicate device. Both devices are used to establish a conduit for irrigation and aspiration of kidney stones during standard ureteroscopy, are composed of biocompatible materials, and are sterile single-use devices.

## 7. TECHNOLOGY CHARACTERISTICS COMPARED TO THE PREDICATE

There are similarities and differences between the technological characteristics of K-VAC and the predicate device. The devices are similar in their use and purpose, as both devices are used to introduce irrigation to fluidize kidney stones and both devices remove stones using aspiration. A few features of the devices are different. **Table 1** on the following page highlights the similarities and differences.

**Table 1. Technology Comparison of K-VAC™ and Predicate Device**

| | **Subject Device**<br>**K-VAC**<br>**(Kalera Medical Inc.)** | **Predicate**<br>**ClearPetra K161110** | **Similar / Different Impact Safety and Effectiveness** |
|---|---|---|---|
| Models and Sizes | One model, two sizes<br>SKU KVAC60: 12F OD, 60 cm<br>SKU KVAC70: 12F OD, 70 cm | ClearPetra Ureteral Access Sheath with 30 SKUs, ranging from 10F to 14F ID, varying lengths | Similar sizes, no impact on safety or effectiveness |
| Design | Dual lumen catheter with Aspiration Connector, Irrigation Port and articulation Control Lever. Radiopaque introducer with a soft, tapered tip. Inserted with introducer over a guidewire under fluoroscopy | Single lumen access sheath with aspiration connector. Irrigation via ureteroscope Radiopaque introducer Inserted with introducer over a guidewire under fluoroscopy | Both devices are similar in the use of luer adapters and connectors, guidewires and introducers, irrigation and aspiration for stone removal and use of fluoroscopy<br>The devices are different in their steerability<br>This difference does not raise any new issues of safety or effectiveness as shown through product testing |
| Lumen Dimension(s) | Dual lumen device, compatible with 12/14F standard ureteral access sheaths<br>• Outer lumen diameter (OD): 12F (4 mm)<br>• Inner lumen diameter (ID): 7.5F (2.5 mm) | Single lumen device<br>Sizes ranging from 10F (3 mm) to 14F (4.7 mm) | Same: K-VAC within size range of predicate |
| Radiopacity | K-VAC and introducer are radiopaque | ClearPetra and introducer are radiopaque | Same |
| Irrigation | Via the Irrigation Port, a luer fitting, using hospital supplies Passive open system design allowing continuous outflow of irrigation fluid | Via the irrigation port of the ureteroscope using hospital supplies<br>Passive open system design allowing continuous outflow of irrigation fluid | Similar method of introducing irrigation with the same goal of fluidizing the kidney stones and fragments<br>Same passive open system design |
| Aspiration | May be used with standard hospital vacuum sources at 150 to 200 mm Hg | May be used with standard hospital vacuum sources at 150 to 200 mm Hg | Same |
| Steerability via actuating distal end | Control Lever can actuate the distal 5 cm of the catheter 180° to each side and can be rotated to access areas of the renal pelvis and calyces | Not steerable.<br>The ureteroscope inside the sheath is steerable and actuates similarly to the subject device | Differences between K-VAC and the predicate devices include:<br>• Steerable tip<br>• A handle lever that controls the actuation of the tip<br>Differences between subject and predicate device were shown not to impact safety or effectiveness of the device. Evidence comes from bench design verification and validation studies and GLP animal study |

## 8. PERFORMANCE TESTING

The 510(k) submission provided performance data to establish the substantial equivalence of K-VAC (the subject device) to the predicate device. A summary of these performance tests is provided below.

***Performance Test Bench (Laboratory Testing):*** Bench performance testing was performed to evaluate dimensional conformance, flow, product cycling, tortuous path testing, actuation testing, torque, and bond testing. Results of verification and validation testing confirm that the aspiration and irrigation and other device characteristics meet product specifications and the device meets design input requirements.

***Performance Testing Animal***: Testing with K-VAC and the predicate device in a GLP Animal Study evaluated device performance under fluoroscopy, irrigation and aspiration using a porcine model. Equivalent pathology and histopathology findings were observed between K-VAC and the predicate device; some observations in both groups were a result of the difficulty in establishing access in a tortuous porcine renal model and were not attributed to either device. Average overall fluoroscopy time and procedure time were substantially equivalent between K-VAC and the predicate device.

***Usability Assessment***: A usability assessment was conducted as a part of the GLP Animal Study, and confirmed that all participants were successful in all tasks during use of K-VAC.

***Biocompatibility Data***: Biocompatibility testing was conducted for K-VAC 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 leads to the conclusion that K-VAC is biocompatible and meets the requirements of ISO 10993-1.

***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 demonstrates the soundness of the product packaging to protect the device and maintain product sterility, integrity and functionality and supports a 12-month shelf life for K-VAC.

## 9. CONCLUSIONS

This 510(k) submission demonstrates that K-VAC is substantially equivalent to the predicate device.